

MYLAN INC.  
Form 10-K  
February 23, 2009

**Table of Contents**

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, DC 20549**

**FORM 10-K**

- Annual Report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934  
For the Fiscal Year Ended December 31, 2008**
- Transition Report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934  
For the transition period from        to        .**

**MYLAN INC.**

(Exact name of registrant as specified in its charter)

**Pennsylvania**

(State or other jurisdiction of incorporation or organization)

**25-1211621**

(I.R.S. Employer Identification No.)

**1500 Corporate Drive, Canonsburg, Pennsylvania 15317**

(Address of principal executive offices)

**Registrant's telephone number, including area code:**

**(724) 514-1800**

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

<b>Title of Each Class:</b>	<b>Name of Each Exchange on Which Registered:</b>
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  No

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

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K 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.

Edgar Filing: MYLAN INC. - Form 10-K

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

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

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

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, 2008, the last business day of the registrant's most recently completed second fiscal quarter was approximately \$3,668,813,108.

The number of outstanding shares of common stock of the registrant as of February 16, 2009, was 304,704,472.

**DOCUMENTS INCORPORATED BY REFERENCE**

<b>Document</b>	<b>Parts of Form 10-K into which Document is Incorporated</b>
Proxy Statement for the 2009 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, 2008.	III

---

MYLAN INC.

INDEX TO FORM 10-K  
For the Year Ended December 31, 2008

	<b>Page</b>
<u>PART I</u>	
<u>ITEM 1.</u>	<u>Business</u> 3
<u>ITEM 1A.</u>	<u>Risk Factors</u> 21
<u>ITEM 1B.</u>	<u>Unresolved Staff Comments</u> 39
<u>ITEM 2.</u>	<u>Properties</u> 39
<u>ITEM 3.</u>	<u>Legal Proceedings</u> 41
<u>ITEM 4.</u>	<u>Submission of Matters to a Vote of Security Holders</u> 44
<u>PART II</u>	
<u>ITEM 5.</u>	<u>Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u> 45
<u>ITEM 6.</u>	<u>Selected Financial Data</u> 47
<u>ITEM 7.</u>	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u> 48
<u>ITEM 7A.</u>	<u>Quantitative and Qualitative Disclosures about Market Risk</u> 70
<u>ITEM 8.</u>	<u>Financial Statements and Supplementary Data</u> 72
<u>ITEM 9.</u>	<u>Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</u> 124
<u>ITEM 9A.</u>	<u>Controls and Procedures</u> 124
<u>ITEM 9B.</u>	<u>Other Information</u> 124
<u>PART III</u>	
<u>ITEM 10.</u>	<u>Directors, Executive Officers and Corporate Governance</u> 124
<u>ITEM 11.</u>	<u>Executive Compensation</u> 124
<u>ITEM 12.</u>	<u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u> 124
<u>ITEM 13.</u>	<u>Certain Relationships and Related Transactions, and Director Independence</u> 124
<u>ITEM 14.</u>	<u>Principal Accounting Fees and Services</u> 125
<u>PART IV</u>	
<u>ITEM 15.</u>	<u>Exhibits and Financial Statement Schedules</u> 125
<u>Signatures</u>	130
<u>EX-10.4(D)</u>	
<u>EX-10.5</u>	
<u>EX-10.7(B)</u>	
<u>EX-10.16(B)</u>	
<u>EX-10.17(D)</u>	
<u>EX-10.18(C)</u>	
<u>EX-10.19(C)</u>	
<u>EX-10.20.C</u>	
<u>EX-10.21(C)</u>	
<u>EX-10.25(D)</u>	

EX-10.26(D)

EX-10.27(B)

EX-10.28(B)

EX-10.32

EX-10.36

EX-21

EX-23

EX-31.1

EX-31.2

EX-32

**Table of Contents**

**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, brand and branded generic pharmaceutical products 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 pharmaceutical company in the world, in terms of revenues. We hold top-five positions in 13 different established markets worldwide and we are building a strong presence in many emerging generics market. This evolution has taken place through organic growth and through 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 acquisitions of Matrix Laboratories Limited (Matrix) and Merck KGaA's generics business (the former Merck Generics business), as further discussed below, 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 listed company in which we have a 71.5% controlling interest, we manufacture and supply low cost, high quality API for our own products and pipeline, as well as for third-parties. Matrix is the world's third largest API manufacturer with respect to the number of drug master files (DMFs) filed with regulatory agencies, with approximately 200 APIs in the market or under development. Matrix is also a leader in supplying API for the manufacturing of anti-retroviral drugs, which are utilized in the treatment of HIV/AIDS. Additionally, 2008 marked the first full year of operations for Matrix's newly launched finished dosage form (FDF) business.

On October 2, 2007, Mylan completed its acquisition of the former Merck Generics business to become one of the largest quality generics and specialty pharmaceutical companies in the world, with a global presence in more than 140 countries and territories. The acquisition of the former Merck Generics business immediately afforded Mylan a worldwide commercial footprint including leadership positions in France and Australia and several other key European and Asia Pacific markets. Mylan markets more than 570 products to consumers in more than 140 countries and territories across the globe. Our products cover a vast array of therapeutic categories, and we offer an extensive range of dosage forms and delivery systems including oral solids, controlled-release, steriles, injectables, topicals, liquids, transdermals, semi-solids and high-potency products. Our product portfolio includes several specialized dosage forms, some of which are difficult to formulate and manufacture and typically have longer product life cycles than traditional generic pharmaceuticals. These dosage forms include high potency formulations, steriles, injectables, transdermal patches, controlled release and respiratory delivery products. We also have 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.

Mylan has three reportable segments, the Generics Segment , the Matrix Segment and the Specialty Segment , as determined in accordance with Statement of Financial Accounting Standards ( SFAS ) No. 131, *Disclosures about Segments of an Enterprise and Related Information*. Refer to Note 17 to Consolidated Financial Statements included elsewhere in this Form 10-K for additional information related to our segments.

## **Table of Contents**

### **Our Operations**

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, Japan and New Zealand (collectively, Asia Pacific). Our specialty pharmaceutical business is conducted by Dey L.P. (Dey), headquartered in Napa, California. Our API business is conducted principally through our majority-owned subsidiary, Matrix, which is headquartered in Hyderabad, India. Docpharma, which is a subsidiary of Matrix, is primarily a distributor of pharmaceutical products in the Benelux region of Europe.

Mylan believes that the breadth and depth of its generics business provides certain competitive advantages over many of its 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 a proprietary API business, which provides vertical integration efficiencies and a high quality, stable supply.

#### *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, and 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.

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 U.S. Food and Drug Administration (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 (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. 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.

## **Table of Contents**

An increasing trend in the pharmaceutical industry involves the practice of authorized generics. This occurs when the patent or New Drug Application ( NDA ) holder sells its brand product as a generic, often through a licensing agreement with a generic company or through a subsidiary, at the same time other generic competition enters the market. This practice has the most significant impact on a generic company that is entitled to the 180-day exclusivity period described above or that would otherwise be the only company on the market with a generic product being sold under an approved ANDA. This practice may effectively eliminate the 180-day exclusivity period if an authorized generic is launched at the beginning of the generic company's exclusivity period and, exclusivity aside, could significantly lower the price at which the generic company could otherwise sell its product upon launch. Additionally, this could affect the extent to which Paragraph IV challenges are pursued by generic companies.

In the U.S., 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 addition, UDL sells several brand products.

In the U.S., we have one of the largest product portfolios among all generic pharmaceutical companies, consisting of approximately 204 products, of which approximately 195 are in capsule or tablet form in an aggregate of approximately 503 dosage strengths. Included in these totals are 22 extended release products in a total of 55 dosage strengths.

In addition to those products that we manufacture in the U.S., we also market, principally through UDL, 73 generic products in a total of 129 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 four transdermal patch products in a total of 22 dosage strengths that are developed and manufactured by MTI. MTI's fentanyl transdermal system was the first AB-rated generic alternative to Duragesic® (fentanyl transdermal system) 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 that 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 with our proven track record of bringing to market products that are difficult to formulate or manufacture or for which the API is difficult to obtain. Over the last 10 years, in addition to fentanyl, we have successfully introduced generic products with high barriers to entry, including our launches of, among others, extended phenytoin sodium, levothyroxine sodium, oxybutynin and paroxetine. 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 U.S. business by launching new products for which we may attain FDA first-to-file status with Paragraph IV certification.

Through Genpharm ULC ( Genpharm ), our wholly-owned Canadian subsidiary acquired as part of the former Merck Generics business acquisition, we manufacture and market generic pharmaceuticals in Canada. Genpharm is the sixth largest generic pharmaceutical company in Canada.

*EMEA*

Our generic pharmaceutical sales in EMEA are derived from our wholly-owned subsidiaries acquired through the acquisition of the former Merck Generics business. We have operations in 25 countries in EMEA. Of the top five

**Table of Contents**

generic pharmaceutical markets in Europe, we hold a top three market share position in four, consisting of France, the United Kingdom ( U.K. ), Spain and Italy.

In France, we market our products through our subsidiaries, Mylan S.A.S. and Qualimed S.A.S., using a sales force of approximately 325 representatives. The French generic pharmaceutical market is primarily a company branded generics market, with pharmacists serving as the key decision makers. France has the third largest generic retail pharmaceutical market in Europe with sales of approximately \$3.17 billion during the twelve months ended October 2008, and we hold the number one market share position, with approximately 200 products in the market.

In the U.K., our subsidiary, Generics [U.K.] Limited, offers a broad product portfolio of more than 385 pharmaceutical products. The U.K. generics pharmaceutical market is a highly competitive traditional generics substitution market, with the wholesalers and pharmacies serving as the key decision makers. The generic retail prescription market had sales of approximately \$3.50 billion for the twelve months ended October 2008, making the U.K. the second largest market in Europe. Prices at the wholesale dealing level are significantly lower. As of October 2008, Generics [U.K.] Limited held an estimated market share of approximately 11%, at the wholesaler dealing level, ranking it as the number two company in the reimbursement market. Generics [U.K.] Limited is well positioned as a preferred supplier to wholesalers and is also focused on areas such as multiple independent retail pharmacies.

In Spain, where we market our products through our subsidiary Mylan Pharmaceuticals S.L., we are the number three ranked company in terms of generic pharmaceutical market share. The Spanish generics market is a company branded generic market, with physicians and/or pharmacists as the key decision makers, depending on the region. The market is focused on brand quality and service level (reliable supply, customer orientation), and it is important to be first-to-market in order to capture market share. The generic retail prescription market in Spain had sales of approximately \$1.10 billion during the twelve months ended October 2008, making it the fourth largest generic market in Europe. The generic market made up approximately 8% of the total Spanish retail pharmaceutical market by sales for the twelve months ended October 2008 and is expected to continue to grow at double digit rates.

In Italy, we are the number three ranked company in terms of generic pharmaceutical market share. The Italian generics market is a branded generic market with a focus on brand quality and the importance of being first-to-market in order to capture and maintain market share. The generic retail prescription market in Italy had sales of approximately \$950.0 million during the twelve months ended October 2008. We believe that the Italian generic market is underpenetrated, with generics representing only 6% of the Italian pharmaceutical retail market. The Italian government has put forth measures aimed at encouraging generic use; however, the scope of these measures is limited and generic substitution is still in its early stages. Some industry observers have projected that the market will grow at approximately 11% per year over the next five years.

In Germany, we market our products through our Mylan dura subsidiary. Most generic products in Germany are sold as brands, with the physician and pharmacist serving as the key decision makers and more recently, with health insurance companies starting to play a major role. The German generic retail prescription market had sales of approximately \$6.20 billion during the twelve months ended October 2008 and is the largest generic market in Europe. As of October 2008, Mylan dura ranked seventh in terms of generic pharmaceuticals market share in Germany. Mylan dura's key therapeutic area strengths include the cardiovascular areas, metabolic disorders, and central nervous system.

We also operate in several other European markets, including Portugal, where we hold a number one ranking, and Belgium, where we hold a number two ranking. We also have a notable presence in the Netherlands, Scandinavia and Ireland. 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 the vertically integrated platform which Matrix provides, will all be keys to our future growth and success in EMEA.

In connection with Mylan's acquisition of the former Merck Generics business, Mylan had the option to acquire several new and emerging Merck Generics businesses within Central and Eastern Europe ( CEE ). On June 2, 2008, Mylan acquired Merck KGaA's CEE generics businesses, which consisted of operations in Poland, Hungary, Slovakia, Slovenia and the Czech Republic.

## **Table of Contents**

In conjunction with the acquisition of the former Merck Generics business, the Company entered into a transitional services agreement ( TSA ) with Merck KGaA that provided for certain general and administrative support in certain countries through October 2, 2008. By September 30, 2008, the various support services being performed under the TSA were terminated as planned. The Company is now performing such services utilizing enhanced support systems.

### *Asia Pacific*

Similar to EMEA, generic pharmaceutical sales in Asia Pacific are derived principally through wholly-owned subsidiaries acquired through the acquisition of the former Merck Generics business. We hold the number one market positions in both Australia and New Zealand and the number four market position in Japan.

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 sales volume as of December 2008, and offering the largest portfolio of generic pharmaceutical products in the Australian market. The Australian generics market is a branded generics market, with the pharmacist serving as the key decision maker. The generics market in Australia is underdeveloped, and as a result, the government is increasingly focused on promoting generics in an effort to reduce costs. The generic pharmaceutical market had sales of approximately \$630.0 million in 2008. Some industry observers have projected that the market will grow at approximately 7% per year over the next five years. In New Zealand, our business operates under the name Pacific Pharmaceuticals Ltd. and is the largest generics company in New Zealand.

Mylan Seiyaku, our Japanese subsidiary, offers a broad portfolio of more than 400 products, with a focus on antibiotics, anti-diabetics, oncology and skin and allergy medications. We have a manufacturing and research and development facility located in Japan, which is key to serving the Japanese market. Japan is the second largest pharmaceutical market in the world and the sixth largest generic market worldwide. The market is currently mostly hospitals, but is expected to move into pharmacies as generic substitution becomes more prevalent. The Japanese generic pharmaceutical market had sales of approximately \$4.1 billion in 2007. Recent pro-generics government actions include higher patient co-pays, fixed hospital reimbursement for certain procedures, and pharmacy substitution. Some industry observers have projected that the generic market will grow at almost 7% per year through 2010. 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.

Approximately 31% and 14% of our Generics Segment net revenues for the nine-month period ended December 31, 2007 and fiscal year ended March 31, 2007, were attributable to calcium channel blockers, primarily nifedipine and amlodipine. Approximately 29% and 19% of our Generics Segment net revenues during the nine-month period ended December 31, 2007, and fiscal year ended March 31, 2007 were attributable to narcotic agonist analgesics, primarily fentanyl.

### *Specialty Segment*

Our specialty pharmaceutical business is conducted through Dey, which competes primarily in the respiratory and severe allergy markets. Dey's products are primarily branded specialty nebulized and injectable products for life-threatening conditions. Dey's revenues since our acquisition have been derived primarily through the sale of EpiPen®.

EpiPen, which is used in the treatment of severe allergies, is an epinephrine auto-injector which has been sold in the United States since 1980 and internationally since the mid-1980's. EpiPen is the number one prescribed treatment for severe allergic reactions with a U.S. market share of more than 95%. The strength of the EpiPen brand name and the promotional strength of the Dey sales force have enabled us to maintain our market share.

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

## **Table of Contents**

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.

Approximately 57% and 27% of the Company's Specialty Segment net revenues for the calendar year ended December 31, 2008 and the nine-month period ended December 31, 2007 were attributable to allergy agents, primarily EpiPen. Approximately 31% and 61% of the Company's Specialty Segment net revenues were attributable to bronchodilators, primarily DuoNeb<sup>®</sup>, Perforomist and albuterol for the calendar year ended December 31, 2008 and the nine-month period ended December 31, 2007.

### *Matrix Segment*

We conduct our API business through Matrix, in which we own a 71.5% interest. Matrix is the world's third largest API manufacturer with respect to the number of DMFs filed with regulatory agencies. Matrix currently has more than 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 ).

Matrix produces API for use in the manufacture of our 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. Also included in Matrix's product portfolio are anti-retroviral ( ARV ) APIs, used in the treatment of HIV. Matrix is a leading supplier of generic ARV APIs.

Matrix has 10 API and intermediate manufacturing facilities and one FDF facility. Of these, eight, including the FDF facility, are FDA approved, making Matrix one of the largest companies in India in terms of FDA-approved API manufacturing capacity. Matrix has manufacturing facilities in China and a distribution facility in Europe.

Our future success in API is dependent upon 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.

Additionally, we view the continued growth of Matrix's FDF business, launched in late 2007, as a key driver of growth, particularly in the ARV market.

### **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. 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.

With the acquisitions of the former Merck Generics business and a controlling interest in Matrix, we have significantly bolstered our global research and development capabilities. Our research and development strategy includes the following areas:

- development of controlled-release technologies and the application of these technologies to reference products;

- development of both NDA and ANDA products;



Edgar Filing: MYLAN INC. - Form 10-K

development of drugs 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 drugs that target smaller, specialized or underserved markets;

development of generic drugs that represent first-to-file opportunities;

expansion of our existing solid oral dosage product portfolio, including with respect to additional dosage strengths;

## **Table of Contents**

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 calendar year ended December 31, 2008, we received 38 application approvals from the FDA, consisting of 24 final ANDA approvals, 13 tentative ANDA approvals and one supplemental ANDA approval.

We have a robust generic product pipeline. In calendar year 2008, we submitted 154 product submissions, which include 72 ANDAs submitted to the FDA. As of December 31, 2008, including Matrix, we had 120 product applications pending at the FDA, representing approximately \$88.0 billion in U.S. sales for the 12 months ended June 30, 2008 for the brand name equivalents of these products, according to IMS Health data. Thirty-two of these applications were first-to-file Paragraph IV ANDA patent challenges, which offer the opportunity for 180 days of generic marketing exclusivity if approved by the FDA and if we are successful in the patent challenge.

## **Product Development and Government Regulation**

### *Generics Segment*

#### *North America*

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.* An 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, and involve changing and evolving standards.

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 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.

## **Table of Contents**

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 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, which became effective January 1, 2006, 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 APIs for use in FDFs to be marketed in the United States is approval of the manufacturing facility in which the APIs 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 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

**Table of Contents**

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 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 was introduced. This second procedure is also led by the RMS, but applications are simultaneously submitted to all selected countries. From 2005, the Centralized Procedure operated by the European

**Table of Contents**

Medicines Agency ( EMA ) became available for generic versions of innovator products approved by the Centralized Procedure.

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 decentralized procedure is based on the same fundamental idea as the MR procedure. In contrast to the MR procedure, however, the decentralized procedure 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 decentralized procedure 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 or decentralized procedures 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 decentralized procedures ( CMD ) and reviewed in a 60-day procedure. If this 60-day procedure does not result in a consensus by all member states, the product can be marketed in the countries whose health authorities agree that the product can be licensed. The issue raised will then enter a second referral procedure.

As with the MR procedure, the advantage of the decentralized procedure 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 decentralized procedure 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 decentralized procedure, 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 repackaging 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 decentralized procedure.



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

**Table of Contents**

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 prescribed minimum targets for generics dispensing.

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. This is true in France and other places, such as 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.

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

## **Table of Contents**

For pharmaceutical products listed on the PBS, the price is determined through negotiations between the Pharmaceutical Benefits Pricing Authority (a governmental agency) and pharmaceutical manufacturers. 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 have been recent changes to the pricing regime for PBS-listed medicines, which have decreased the margin wholesalers can charge. 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 of pharmaceutical products are also regulated by the Therapeutic Goods Administration (TGA), under the Therapeutic Goods Act 1989 (Cth) (Act). The TGA 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 4 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 of information about therapeutic goods for human use that are approved for supply in, or export from, Australia. Whether a product is listed or registered in the ARTG depends largely on the ingredients, the dosage form of the product and the promotional or therapeutic claims made for the product.

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

Labeling, packaging and advertising of pharmaceutical products are also regulated by the TGA.

In Japan, we are governed by various laws and regulations, including the Pharmaceutical Law and the Products Liability Law.

Under the Pharmaceutical 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 Ministry of Health, Labour and Welfare (Ministry). A Marketing License includes a manufacturing license. There are two types of Marketing Licenses according to the pharmaceuticals to be marketed. 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 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, 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 bioequivalency study) 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.

## **Table of Contents**

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 Ministry 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 Ministry must seek the opinion of the Pharmaceutical Affairs and Food Sanitation Council.

The Pharmaceutical Law provides that when the pharmaceutical that is the subject of an application is shown not to result in the indicated effects or performance indicated in the application, or when the pharmaceutical is found to have no value as a pharmaceutical because it has harmful effects outweighing its indicated effects or performance, Marketing Approval shall not be granted.

The Ministry can order the cancellation or amendment of a Marketing Approval when (1) it is necessary to do so from the viewpoint of public health and hygiene, (2) the necessary materials for re-examination or re-valuation, 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 Ministry, (3) the relevant company's Marketing License has expired or has been canceled (a Marketing License needs to be renewed every five years), (4) the regulations regarding investigations of facilities in relation to manufacturing management standards or quality control have been violated or (5) the conditions set in relation to the Marketing Approval have been violated.

Doctors and pharmacists providing medical services pursuant to state medical insurance are prohibited from using pharmaceuticals other than those specified by the Ministry. The Ministry 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, are revised every two years.

### *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 United States 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

## **Table of Contents**

30 days after receipt by the FDA unless the FDA, during that 30-day period, raises concerns or questions about the conduct of the proposed trials, as outlined in the IND. In such cases, the IND sponsor and the FDA must resolve any outstanding concerns before clinical trials may begin. In addition, an independent institutional review board must review and approve any clinical study prior to initiation.

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

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

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

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

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

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. Certain suppliers are subject to similar regulations and periodic inspections.

*Matrix Segment*

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

## **Table of Contents**

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. During the calendar year ended December 31, 2008, Matrix filed 20 DMFs in the U.S. and 42 DMFs/Certification of Suitability of European Pharmacopoeia Monographs in the rest of the world.

## **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 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.

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 that we may possess 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 can be renewed indefinitely.

As part of the former Merck Generics business acquisition, we entered into a Brand License Agreement with Merck KGaA which generally grants us the right to use the Merck name for the acquired businesses for a period of up to two years from the date the acquisition was consummated. As such, the Company has developed and is implementing a country by country re-branding plan that includes regulatory, logistical and marketing aspects,

## **Table of Contents**

including renaming certain of the acquired businesses, re-labeling certain products and incurring certain other related costs.

## **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, pharmacy groups, 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.

During the calendar year ended December 31, 2008, sales to McKesson Corporation and Cardinal Health, Inc. represented 12% and 10% of consolidated net revenues. Sales to Cardinal Health, Inc. and McKesson Corporation represented 11% and 16% of consolidated net revenues during the nine months ended December 31, 2007. Sales to AmerisourceBergen Corporation, Cardinal Health, Inc. and McKesson Corporation represented approximately 13%, 18% and 19%, respectively, of consolidated net revenues in fiscal 2007.

### *Matrix Segment*

Our APIs are sold primarily to generic FDF manufacturers throughout the world.

### *Specialty Segment*

Dey markets its products to the same types of customers as our Generics Segment. Additionally, national and regional health home care are important customers for our nebulized products. Through our approximately 280 employee field-based sales force, we market to health care practitioners, to increase their understanding of the unique clinical characteristics 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 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.

## **Competition**

Our primary competitors include other generic companies (several 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

**Table of Contents**

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 brand 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 in different countries. 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.

*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.

*Germany.* The German market has become highly competitive as a result of a large number of generic players and one of the highest generic penetration rates in Europe. The German market is primarily branded generics, with physicians and pharmacists having a great deal of influence over which company's products are dispensed. Recent legislation has resulted in pricing pressures, which, along with the desire by health insurers to deal with a select number of generic suppliers, should drive near-term competition.

*Spain.* Spain is a rapidly growing, highly fragmented generic market with over 100 market participants. Certain regions permit generic substitution by pharmacists, while others do not. As such, physicians and/or pharmacists are the key 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.

*Italy.* The Italian generic market is relatively small due 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 measures aimed at increasing generic usage; however, generic substitution is still in its early stages.

*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 Indian pharmaceutical industry growth will be led by the export of API and generic FDF products to developed markets. 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.

## **Table of Contents**

### **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. The purchase of a controlling interest in 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.

### **Seasonality**

Our business is not materially affected by seasonal factors.

### **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 earnings or competitive position.

### **Employees**

We currently employ more than 15,000 people globally, made up of approximately 12,000 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**



Edgar Filing: MYLAN INC. - Form 10-K

The Company maintains an Internet website at the following address: [www.mylan.com](http://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

**Table of Contents**

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](http://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 is currently undergoing a period of unprecedented volatility, and the future economic environment may continue to be less favorable than that of recent 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.

**OUR ACQUISITION OF THE FORMER MERCK GENERICS BUSINESS INVOLVES A NUMBER OF INTEGRATION 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 acquisition of the former Merck Generics business involves a number of integration risks, 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 and business applications and the build up of additional corporate infrastructure;

difficulties in transitioning the former Merck Generics business and products from the Merck name to achieve a global brand alignment;

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 United States 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

**Table of Contents**

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 A CONTROLLING INTEREST IN MATRIX. ANY SUCH FAILURE 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.**

The success of the acquisitions of the former Merck Generics business and a controlling interest in 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.

**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 a controlling interest in 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 is 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 EXPANSION THROUGH THE ACQUISITIONS OF THE FORMER MERCK GENERICS BUSINESS AND A CONTROLLING INTEREST IN MATRIX 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.**

With our acquisitions of the former Merck Generics business and a controlling interest in Matrix, our operations extend to numerous countries outside the United States. 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;

**Table of Contents**

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 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 FDA in the United States and the EMA in the EU). The process of obtaining regulatory approval to manufacture and market new and generic pharmaceutical products is rigorous, time consuming, costly and largely unpredictable. Outside the United States, 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 United States. 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

**Table of Contents**

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 United States, 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 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 United States, 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.

**OUR APPROVED PRODUCTS MAY NOT ACHIEVE EXPECTED LEVELS OF MARKET ACCEPTANCE, WHICH COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR PROFITABILITY,**

**Table of Contents**

**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 international 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.

**Table of Contents**

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.

**OUR REPORTING AND PAYMENT OBLIGATIONS UNDER THE MEDICARE AND/OR MEDICAID REBATE PROGRAM AND OTHER GOVERNMENTAL PURCHASING AND REBATE PROGRAMS**

**Table of Contents**

**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. As discussed elsewhere in this Form 10-K and other reports we file with the SEC, we and other pharmaceutical companies are defendants in a number of suits filed by state attorneys general and have been notified of an investigation by the United States Department of Justice with respect to Medicaid reimbursement and rebates. While we cannot predict the outcome of the investigation, possible remedies which the United States government could seek include treble damages, civil monetary penalties and exclusion from the Medicare and Medicaid programs. In connection with such an investigation, the United States government may also seek a Corporate Integrity Agreement (administered by the Office of Inspector General of Health and Human Services) with us which could include ongoing compliance and reporting obligations. 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. Typically, research expenses related to the development of innovative compounds and the filing of marketing authorization applications for innovative compounds (such as NDAs in the United States) are significantly greater than those expenses

**Table of Contents**

associated with the development of and filing of marketing authorization applications for generic products (such as ANDAs in the United States and abridged applications in Europe). As we continue to develop new products, our research expenses will likely increase. Because of the inherent risk associated with research and development efforts in our industry, particularly with respect to new drugs our, or a partner's, research and development expenditures may not result in the successful introduction of new pharmaceutical products approved by the relevant regulatory bodies. Also, after we submit a marketing authorization application for a new compound or generic product, the relevant regulatory authority may 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;

**Table of Contents**

persuading regulatory bodies to withdraw the approval of brand name drugs for which the patents are about to expire, thus allowing the brand name company to obtain new patented products serving as substitutes for the products withdrawn; and

seeking to obtain new patents on drugs for which patent protection is about to expire.

In the United States, 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 United States, 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 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

**Table of Contents**

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.

**WE MAY DECIDE TO SELL ASSETS WHICH COULD ADVERSELY AFFECT OUR PROSPECTS AND OPPORTUNITIES FOR GROWTH, 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 THE MARKET VALUE OF OUR COMMON STOCK COULD 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 domestic and international 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

**Table of Contents**

position and results of operations to be materially adversely affected, and the market value of our common stock could decline. In addition, our manufacturing capabilities could be impacted by quality deficiencies in the products which our suppliers provide, which could have a material adverse effect on our business, financial position and results of operations, and the market value of our common stock could decline.

We utilize controlled substances in certain of our current products and products in development and therefore must meet the requirements of the Controlled Substances Act of 1970 and the related regulations administered by the DEA in the United States 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 EFFORTS TO TRANSITION THE FORMER MERCK GENERICS BUSINESS SUBSIDIARIES AWAY FROM THE MERCK NAME INVOLVE INHERENT RISKS AND MAY RESULT IN GREATER THAN EXPECTED COSTS OR IMPEDIMENTS, WHICH COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS, FINANCIAL POSITION AND RESULTS OF OPERATIONS AND COULD CAUSE THE MARKET VALUE OF OUR COMMON STOCK TO DECLINE.**

We have a license from Merck KGaA to continue using the Merck name, including in product names, in respect of the former Merck Generics businesses for a transitional period of two years after the closing of the acquisition. We are engaged in efforts to transition in an orderly manner away from the Merck name and to achieve global brand alignment. Re-branding may prove to be costly, especially in markets where the former Merck Generics business name has strong dominance or significant equity locally. In addition, brand migration poses risks of both business disruption and customer confusion. Our customer outreach and similar efforts may not mitigate fully the risks of the name changes, which may lead to reductions in revenues in some markets. These losses 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 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.**

**Table of Contents**

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 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 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. 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**

**Table of Contents**

**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 United States, 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 United States, 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 Germany, recent legislative changes have been introduced which are aimed at reducing costs for the German statutory health insurance, or SHI, scheme. The measure is likely to have an impact upon marketing practice and reimbursement of drugs and may increase pressure on competition and reimbursement margins. These 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.

In the U.K., the Office of Fair Trading ( OFT ) produced recommendations in February 2007 that suggested that the U.K. should include off patent brands in its value based pricing structure in addition to generics, for the reimbursement of pharmaceutical products. The desired effect is to reduce the difference between the reimbursement levels of off patent brands and generics. This will increase the generics industry's ability to compete with off patent brands on a level playing field. Generics [U.K.] Ltd. and the BGMA (British Generics Manufacturers Association) support the OFT in this recommendation.

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 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 United States 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.

**Table of Contents**

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.

In July 2008, the Australian government mandated a 25% price reduction on 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.

**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 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.

The EU is conducting a pharmaceutical sector inquiry involving approximately 100 companies concerning the introduction of innovative and generic medicines. Mylan's subsidiary, Mylan S.A.S, acting on behalf of Mylan EU affiliates, has responded to questionnaires and has produced documents and other information in connection with the inquiry. The Commission has not alleged that the Company or any of its EU subsidiaries have engaged in any unlawful practices. Matrix has likewise received a request for information from the EU Commission. If this inquiry was 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.

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. This 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.

**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

**Table of Contents**

obligation under an indemnification provision exceed our coverage or should coverage be denied, our business, financial position and results of operations could be materially adversely affected and the market value of our common stock could decline.

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

It is important that we attract and retain qualified personnel in order to develop new products and compete effectively. If we fail to attract and retain key scientific, technical or management personnel, our business could be affected adversely. Additionally, while we have employment agreements with certain key employees in place, their employment for the duration of the agreement is not guaranteed. If we are unsuccessful in retaining our key employees, it could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

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

We are enhancing and further developing our global enterprise resource planning ( ERP ) systems and associated applications to provide more operating efficiencies and effective management of our business operations. Such changes to ERP systems and related software carry risks such as cost overruns, project delays and business interruptions and delays. If we experience a material business interruption as a result of our ERP enhancements, it could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

**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, 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, 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.

**Table of Contents**

**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 and the market price of our securities 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. Matrix's ability to recruit, train and retain qualified employees and develop and operate its manufacturing facilities 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. Such 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 our share price and/or 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, our costs and our indebtedness are denominated in foreign currencies including the Euro, the Australian dollar, the British pound, the Canadian dollar, the Indian Rupee and the Japanese Yen. We report our financial results in U.S. dollars. Our results of operations and, in some cases, cash flows, 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, 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

**Table of Contents**

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 United States 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 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 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.

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 MUST MAINTAIN ADEQUATE INTERNAL CONTROLS AND BE ABLE, ON AN ANNUAL BASIS, TO PROVIDE AN ASSERTION AS TO THE EFFECTIVENESS OF SUCH CONTROLS. FAILURE TO MAINTAIN ADEQUATE INTERNAL CONTROLS OR TO IMPLEMENT NEW OR IMPROVED CONTROLS COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS, FINANCIAL**

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

Effective internal controls are necessary for 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 United States 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

**Table of Contents**

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 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.

Although the conversion feature under our Senior Convertible Notes is not marked to market, as the price of our common stock 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 Notes 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,

**Table of Contents**

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 accounting principles generally accepted in the United States of America ( 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 (including acquired in-process research and development) 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. 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 (including acquired in-process research and development) 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 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 research and development, manufacturing, warehousing, distribution and administrative functions. These facilities consist of both owned and leased properties.

**Table of Contents**

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

<b>Primary Segment</b>	<b>Location</b>	<b>Status</b>	<b>Primary Use</b>
<b>Generics Segment</b>	North Carolina	Owned	Distribution, Warehousing
	West Virginia	Owned	Manufacturing, R&D, Warehousing, Administrative
	Illinois	Owned	Manufacturing, Warehousing, Administrative
	Texas	Owned	Manufacturing, Warehousing
	Vermont	Owned	Manufacturing, R&D, Warehousing, Administrative
	Puerto Rico	Owned	Manufacturing, Warehousing, Administrative
	Germany	Leased	Administrative, Warehousing
	France	Owned	Manufacturing
		Leased	Administrative
	United Kingdom	Leased	Manufacturing, R&D, Warehousing, Administrative
	Ireland	Owned	Manufacturing, Distribution, Warehousing, Administrative
		Leased	Warehousing
	Australia	Owned	Manufacturing, R&D, Distribution, Warehousing, Administrative
		Leased	R&D, Manufacturing, Warehousing, Administrative
	Netherlands	Leased	Distribution, R&D, Warehousing, Administrative
	Canada	Owned	Manufacturing, R&D, Distribution, Warehousing, Administrative
		Leased	Distribution, Warehousing
New Zealand	Leased	Distribution, Warehousing, Administration	
India	Owned	Manufacturing, R&D, Distribution, Warehousing, Administrative	
Japan	Owned	Manufacturing, R&D, Administrative, Warehousing	
	Leased	Warehousing, Administrative	
<b>Specialty Segment</b>	California	Owned	Manufacturing, R&D, Warehousing, Administrative, Distribution
	Texas	Leased	Distribution, Warehousing
<b>Matrix Segment</b>	China	Owned	Manufacturing, Warehousing, Administrative
		Leased	Manufacturing
	India	Owned	Manufacturing, R&D, Warehousing, Administrative
		Leased	R&D, Administrative
	Belgium	Leased	Warehousing, Administrative
	Netherlands	Leased	Warehousing, Administrative



Edgar Filing: MYLAN INC. - Form 10-K

<b>Corporate/Other</b>	Luxembourg	Leased	Warehousing, Administrative
	Pennsylvania	Owned	Administrative
	New Jersey	Leased	Administrative
	New York	Leased	Administrative

**Table of Contents**

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.

*Omeprazole*

On May 17, 2000, MPI filed an ANDA seeking approval from the FDA to manufacture, market and sell omeprazole delayed-release capsules and on August 8, 2000 made Paragraph IV certifications to several patents owned by AstraZeneca PLC ( AstraZeneca ) that were listed in the FDA's Orange Book. On September 8, 2000, AstraZeneca filed suit against MPI and Mylan in the U.S. District Court for the Southern District of New York alleging infringement of several of AstraZeneca's patents. On May 29, 2003, the FDA approved MPI's ANDA for the 10 mg and 20 mg strengths of omeprazole delayed-release capsules, and, on August 4, 2003, Mylan announced that MPI had commenced the sale of omeprazole 10 mg and 20 mg delayed-release capsules. AstraZeneca then amended the pending lawsuit to assert claims against Mylan and MPI and filed a separate lawsuit against MPI's supplier, Esteve Quimica S.A. ( Esteve ), for unspecified money damages and a finding of willful infringement. MPI has certain indemnity obligations to Esteve in connection with this litigation. On May 31, 2007, the district court ruled in Mylan's and Esteve's favor by finding that the asserted patents were not infringed by Mylan's/Esteve's products. On July 18, 2007, AstraZeneca appealed the decision to the United States Court of Appeals for the Federal Circuit. On June 10, 2008, the appellate court issued a judgment and decision affirming the district court's finding of noninfringement and the mandate was issued on July 1, 2008.

*Lorazepam and Clorazepate*

On June 1, 2005, a jury verdict was rendered against Mylan, 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, 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 \$9.0 million. The Company and its co-defendants have appealed to the U.S. Court of Appeals for the D.C. Circuit. The appeals have been held in abeyance pending a ruling on the motion for prejudgment interest. 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, 2008) and an irrevocable letter of

## **Table of Contents**

credit for \$34.5 million issued under the Senior Credit Agreement. On October 27, 2008, a U.S. magistrate judge issued a report recommending the granting of plaintiffs' motion for prejudgment interest. The report also recommends requiring the surety bond amount to be increased to include prejudgment interest. Mylan has submitted objections to the magistrate judge's recommendations and now pending is the district court's determination of whether to accept or reject those recommendations. If the magistrate's recommendations on prejudgment interest are accepted, Mylan intends to contest these rulings as part of its pending appeal.

### *Pricing and Medicaid Litigation*

On June 26, 2003, MPI and UDL received requests from the U.S. House of Representatives Energy and Commerce Committee (the Committee) seeking information about certain products sold by MPI and UDL in connection with the Committee's investigation into pharmaceutical reimbursement and rebates under Medicaid. MPI and UDL cooperated with this inquiry and provided information in response to the Committee's requests in 2003. Several states' attorneys general (AG) have also sent letters to MPI, UDL and Mylan Bertek Pharmaceuticals Inc., demanding that those companies retain documents relating to Medicaid reimbursement and rebate calculations pending the outcome of unspecified investigations by those AGs into such matters. In addition, in July 2004, Mylan received subpoenas from the AGs of California and Florida in connection with civil investigations purportedly related to price reporting and marketing practices regarding various drugs. As noted below, both California and Florida subsequently filed suits against Mylan, and the Company believes any further requests for information and disclosures will be made as part of that litigation.

Beginning in September 2003, Mylan, MPI and/or UDL, together with many other pharmaceutical companies, have been named in civil lawsuits filed by state 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. 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 an unspecified amount in money damages, civil penalties and/or treble damages, counsel fees and costs, and injunctive relief. In each of these matters Mylan, MPI and/or UDL either have either moved to dismiss the complaints or have answered the complaints denying liability. Mylan and its subsidiaries intend to defend each of these actions vigorously.

In May 2008, an amended complaint was filed in the U.S. District Court for the District of Massachusetts by a 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 recovery of any and all alleged overpayment of the federal share under the Medicaid program. Mylan has moved to dismiss the complaint and intends to defend the action vigorously.

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 involves whether MPI and UDL may have violated the False Claims Act or other laws by classifying certain authorized generics launched in the 1990's and early 2000's as non-innovator rather than innovator drugs for purposes of Medicaid and other federal healthcare programs

until 2005. MPI and UDL deny the government's allegations and deny that they engaged in any wrongful conduct. Based on our understanding of the government's allegations, the alleged difference in rebates for the MPI and UDL products currently at issue may be up to approximately \$100.0 million, which includes interest. Remedies under the False Claims Act could include treble damages and penalties. MPI and UDL have been cooperating fully with the government's investigation and are currently in discussions with the government about a

**Table of Contents**

possible resolution of the matter. Additionally, the Company believes that it has contractual and other rights to recover from the innovator a substantial portion of any payments that MPI and UDL may remit to the government. The Company has not recorded any amounts in the consolidated financial statements related to this matter.

Dey is a defendant currently in lawsuits brought by the state AG's of Arizona, California, Florida, Illinois, Iowa, Kansas, Kentucky, Pennsylvania, South Carolina (on behalf of the state and the state health plan), Utah and Wisconsin and 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 most of these class actions, which has been preliminarily approved by the court. Additionally, the U.S. federal government filed a claim against Dey in August 2006. These cases all generally allege that Dey falsely reported certain price information concerning certain drugs marketed by Dey. Dey intends to defend each of these actions vigorously. In conjunction with the former Merck Generics business acquisition by Mylan, Mylan is entitled to indemnification by Merck KGaA for these Dey pricing related suits.

The Company has approximately \$118.6 million recorded in other liabilities related to the pricing-related litigation involving Dey. As stated above, in conjunction with the former Merck Generics business acquisition, Mylan is entitled to indemnification from Merck KGaA under the Share Purchase Agreement. As a result, the Company has recorded approximately \$119.7 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 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 action are pending, with the exception of the third-party payor action, in which Mylan's response to the complaint is not due until the motions filed in the other cases have been decided. 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 MTI 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 is cooperating 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*

In March 2004, Mylan Inc. and MPI, along with Dr. Reddy's Laboratories, Inc., were named in a civil lawsuit filed in the Northern District of Georgia by UCB Society Anonyme and UCB Pharma, Inc. (UCB) alleging infringement of U.S. Patent No. 4,943,639 relating to levetiracetam tablets. This litigation was settled in October 2007. Under the terms of the settlement, Mylan was granted the right to market 250 mg, 500 mg, and 750 mg levetiracetam tablets in the United States beginning on November 1, 2008, provided that UCB obtained pediatric exclusivity for its product and Mylan obtained final approval for its ANDA from the FDA. Pediatric exclusivity has been granted. In addition, by letter dated November 19, 2007, Mylan was notified by the FTC of an investigation relating to the settlement of the levetiracetam patent litigation. In its letter, the FTC requested certain information from Mylan pertaining to the patent

litigation and the settlement thereof. On April 9, 2008, the FTC issued a civil investigative demand requesting additional information from Mylan relating to the investigation. Mylan is cooperating fully with the government's investigation and has complied with all requests for information. Mylan launched its 250 mg, 500 mg, and 750 mg levetiracetam tablet products in November 2008.

## **Table of Contents**

### *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 is 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, approximately 198 lawsuits have been filed against Mylan, UDL and Actavis pertaining to the recall. An adverse outcome in these lawsuits or the inability or denial of Actavis to pay on an indemnified claim could have a materially adverse effect on our financial position and results of operations.

### *Pioglitazone*

On February 21, 2006, a district court in the United States District Court for the Southern District of New York held that Mylan, MPI and UDL's pioglitazone ANDA product infringed a patent asserted against them by Takeda Pharmaceuticals North America, Inc. and Takeda Chemical Industries, Ltd (hereinafter, Takeda) and that the patent was enforceable. That same court also held that Alphapharm Pty, Ltd and Genpharm, Inc.'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. 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. Although the required amounts have been paid, Mylan and Alphapharm/Genpharm intend to continue to challenge the exceptional case findings by filing petitions for writ of certiorari with the United States Supreme Court.

### *Litigation related to the former Merck Generics Business*

*Generics UK Ltd.* was accused of having been involved in pricing agreements pertaining to certain drugs during the years 1996 to 2000. Generics UK Ltd. was able to settle civil claims for damages brought by the National Health Service in England, and Wales, and health authorities in Scotland and Northern Ireland out of court, without any admission of liability. In addition to these civil claims, in 2006 criminal proceedings were filed in Southwark Crown Court against Generics UK Ltd. and other companies, as well as against a number of individuals who were alleged to be responsible for decision making in the companies. In early 2008, the House of Lords ruled that a price fixing cartel was not at the relevant times a criminal offense. The case was remanded back to the Crown Court for the prosecution to make an application to amend the indictment. On July 11, 2008, the Crown Court refused to allow the prosecution's application, quashed the indictment and denied the prosecution's application for permission to appeal. On July 17, 2008, the prosecution applied to the Court of Appeal (Criminal Division) for permission to appeal. On December 3, 2008, the Court of Appeal denied the prosecution's application for permission to appeal. Accordingly, all civil and criminal proceedings relating to the above described pricing agreements have now been either terminated or resolved.

### *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 former Merck Generics business acquisition. While it is not possible 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 or results of operations.

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



None.

**Table of Contents****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:

<b>Calendar Year Ended December 31, 2008</b>	<b>High</b>	<b>Low</b>
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

<b>Twelve Months Ended December 31, 2007</b>	<b>High</b>	<b>Low</b>
Three months ended March 31, 2007	\$ 22.75	\$ 19.18
Three months ended June 30, 2007	22.90	17.95
Three months ended September 30, 2007	18.34	13.88
Three months ended December 31, 2007	17.30	12.93

As of February 16, 2009, there were approximately 170,008 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, 2008:

<b>Plan Category</b>	<b>Number of Securities to be Issued upon Exercise of Outstanding Options, Warrants and Rights</b>	<b>Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights</b>	<b>Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (excluding securities reflected in column (a))</b>
Equity compensation plans approved by	25,760,799	\$ 13.93	20,715,362

security holders  
Equity compensation  
plans not approved by  
security holders

Total	25,760,799	\$	13.93	20,715,362
-------	------------	----	-------	------------

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

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 ).

In conjunction with Mylan s acquisition of a controlling interest in Matrix, certain selling shareholders agreed to purchase approximately 8.1 million unregistered shares of Mylan Inc. common stock for approximately \$168.0 million. The exemption from registration was pursuant to Section (4)(2) of the Securities Act. Each of these selling shareholders represented to Mylan that it was an accredited investor. The stock was subsequently registered.

**Table of Contents****STOCK PERFORMANCE GRAPH**

Set forth below is a performance graph comparing the cumulative total returns (assuming reinvestment of dividends) for the four fiscal years ended March 31, 2007, the nine-month period ended December 31, 2007 and the calendar year ended December 31, 2008 of \$100 invested on March 31, 2003 in Mylan's Common Stock, the Standard & Poor's 500 Composite Index and the Dow Jones U.S. Pharmaceuticals Index.

\* \$100 invested on 3/31/03 in stock or index-including reinvestment of dividends.

	<b>3/03</b>	<b>3/04</b>	<b>3/05</b>	<b>3/06</b>	<b>3/07</b>	<b>12/07</b>	<b>12/08</b>
Mylan Inc.	100.00	119.11	93.46	124.88	114.15	76.17	53.58
S&P 500	100.00	135.12	144.16	161.07	180.13	188.81	118.96
Dow Jones US Pharmaceuticals	100.00	106.38	99.28	101.24	112.57	117.27	95.99

**Table of Contents****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.

	<b>Calendar Year Ended<sup>(1)</sup> December 31, 2008</b>	<b>Nine Months Ended<sup>(2)</sup> December 31, 2007</b>	<b>Fiscal Year Ended March 31,</b>		
			<b>2007<sup>(3)</sup></b>	<b>2006<sup>(4)</sup></b>	<b>2005<sup>(4)</sup></b>
<i>(In thousands, except per share amounts)</i>					
Statements of Operations:					
Total revenues	\$ 5,137,585	\$ 2,178,761	\$ 1,611,819	\$ 1,257,164	\$ 1,253,374
Cost of sales	3,067,364	1,304,313	768,151	629,548	629,834
Gross profit	2,070,221	874,448	843,668	627,616	623,540
Operating expenses:					
Research and development	317,217	146,063	103,692	102,431	88,254
Acquired in-process research and development		1,269,036	147,000		
Goodwill impairment	385,000				
Selling, general and administrative	1,053,485	449,598	215,538	225,380	259,105
Litigation settlements, net	16,634	(1,984)	(50,116)	12,417	(25,990)
Earnings (loss) from operations	297,885	(988,265)	427,554	287,388	302,171
Interest expense	357,045	179,410	52,276	31,285	
Other income, net	11,337	86,611	50,234	18,502	10,076
(Loss) earnings before income taxes and minority interest	(47,823)	(1,081,064)	425,512	274,605	312,247
Income tax provision	137,423	60,073	208,017	90,063	108,655
Minority interest (income) expense	(4,031)	(3,112)	211		
Net (loss) earnings before preferred dividends	(181,215)	(1,138,025)	217,284	184,542	203,592
Preferred dividends	139,035	15,999			
Net (loss) earnings available to common shareholders	\$ (320,250)	\$ (1,154,024)	\$ 217,284	\$ 184,542	\$ 203,592

Edgar Filing: MYLAN INC. - Form 10-K

Selected Balance Sheet data:

Total assets	\$	10,409,859	\$	11,353,176	\$	4,253,867	\$	1,870,526	\$	2,135,673
Working capital		1,630,023		1,056,950		1,711,509		926,650		1,282,945
Short-term borrowings		151,109		144,355		108,259				
Long-term debt, including current portion of long-term debt		5,168,800		5,112,094		1,776,362		687,938		
Total shareholders equity		2,703,509		3,403,426		1,648,860		787,651		1,845,936
Per common share data:										
(Loss) earnings available to common shareholders										
Basic	\$	(1.05)	\$	(4.49)	\$	1.01	\$	0.80	\$	0.76
Diluted	\$	(1.05)	\$	(4.49)	\$	0.99	\$	0.79	\$	0.74
Cash dividends declared and paid	\$		\$	0.06	\$	0.24	\$	0.24	\$	0.12
Weighted average common shares outstanding:										
Basic		304,360		257,150		215,096		229,389		268,985
Diluted		304,360		257,150		219,120		234,209		273,621

(1) Calendar year 2008 cost of sales includes approximately \$415.6 million (pre-tax) 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 non-cash goodwill impairment loss of \$385.0 million (pre-tax and after tax) and non-cash impairment charges on certain other assets of \$72.5 million (pre-tax).

**Table of Contents**

- (2) 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 (pre-tax and after tax), cost of sales includes approximately \$148.9 million (pre-tax) 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.
- (3) 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 (pre-tax and after tax), cost of sales includes approximately \$17.6 million (pre-tax) related to the amortization of intangibles and the inventory step-up primarily associated with the acquisition.
- (4) Fiscal year 2006 and fiscal year 2005 do not include stock-based compensation expense as required by SFAS No. 123 (revised 2004), as the adoption of this standard did not occur until April 1, 2006 and the Company elected the prospective method.

**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 the Company's 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 the Company's 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, believe, anticipate, expect, plan, estimate, forecast, potential, intend, continue and variati comparable 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 II, Item 1A. The Company undertakes no obligation to update any forward-looking statements for revisions or changes after the date of this Form 10-K.

**Executive Overview**

We are a leading global pharmaceutical company and have developed, manufactured, marketed, licensed and distributed high quality generic, branded and branded generic pharmaceutical products for more than 45 years. As a result of our acquisition of the former Merck Generics business in October 2007 and the acquisition of a controlling interest in Matrix in January 2007, we are a leader in branded specialty pharmaceuticals and the third largest active pharmaceutical ingredient (API) manufacturer with respect to the number of drug master files (DMFs) filed with regulatory agencies. We hold a leading generics sales position in four of the world's largest pharmaceutical markets, those being the United States (U.S.), the United Kingdom (U.K.), France and Japan, and we also hold leading sales positions in several other key generics markets, including Australia, Belgium, Italy, Portugal and Spain.

Mylan has three reportable segments: the Generics Segment, the Specialty Segment, and the Matrix Segment, as determined in accordance with Statement of Financial Accounting Standards (SFAS) No. 131, *Disclosures about Segments of an Enterprise and Related Information*. Certain general and administrative expenses, as well as litigation settlements, revenue related to the sale of Bystolic rights, amortization of intangible assets and certain purchase

accounting items (such as the write-off of in-process research and development and the amortization of the inventory step-up), non-cash impairment charges, and other expenses not directly attributable to the segments are reported in Corporate/Other.

The measure of profitability used by the Company with respect to segments is gross profit less direct research and development expenses ( R&D ) and direct selling, general and administrative expenses ( SG&A ).



**Table of Contents**

**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 2008     January 1, 2008 through December 31, 2008;

calendar year 2007   or   comparable twelve-month period     January 1, 2007 through December 31, 2007;

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

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

fiscal 2007     April 1, 2006 through March 31, 2007.

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, the Company believes 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 the Company's 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 and from a comparison of the transition period to fiscal 2007, respectively.

An overview of fiscal 2007 is also provided below in order to highlight certain trends and the effects on that year of the Matrix transaction which are not in the comparable nine-month period.

**Bystolic®**

In January 2006, the Company 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.

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 one-time 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. The Company believes that it no longer has 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 the Company's Consolidated Statements of Operations during 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.

## **Table of Contents**

### **Issuance of Cash Convertible Notes**

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 ).

The Cash Convertible Notes, which are unsecured, pay interest semi-annually at a rate of 3.75% per annum and mature on September 15, 2015. The Cash Convertible Notes are convertible under certain circumstances into cash at an initial conversion reference rate of 75.0751 shares of Mylan's common stock per \$1,000 principal amount of notes (which is equal to an initial conversion reference price of approximately \$13.32 per share). The Cash Convertible Notes are not convertible into shares of Mylan common stock or any other securities.

### **Goodwill Impairment**

On February 27, 2008, the Company announced that it was reviewing strategic alternatives for its 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 in accordance with SFAS No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets* ( SFAS No. 144 ). 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 under the provisions of SFAS No. 131. Dey is also considered a reporting unit under the provisions of SFAS No. 142, *Goodwill and Other Intangible Assets* ( SFAS No. 142 ). Upon closing of the transaction, the Company allocated \$711.2 million of goodwill to Dey.

The Company tests 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, the Company was 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 SFAS No. 142 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.

*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.

**Table of Contents**

Based on the SFAS No. 142 step one analysis that was performed for Dey, the Company determined that the carrying amount of the net assets of the reporting unit was in excess of its estimated fair value. As such, the Company was 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, the Company concluded that \$385.0 million of the goodwill recorded at Dey was impaired. As a result, the Company recorded a non-cash 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 the Company's Consolidated Balance Sheet, other than goodwill, as a result of this process.

The determination of the fair value of the reporting unit required the Company 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 the Company 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, the Company announced its decision to retain the Dey business. This decision included a plan to realign the business, including positioning the Company to divest Dey's current facilities over the next two years. As a result, the Company expects to incur severance and other exit costs. In addition, the comprehensive review resulted in a non-cash impairment of certain non-core, insignificant, third-party products.

***Levetiracetam Launch***

On November 4, 2008, the Company announced that its wholly-owned subsidiary, Mylan Pharmaceuticals Inc. ( MPI ), received final approval from the U.S. Food and Drug Administration ( FDA ) for its Abbreviated New Drug Application ( 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 12 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.

***Other Product Opportunities***

On December 2, 2008, the Company announced that Mylan and MPI have entered into a settlement agreement with Novartis Pharmaceuticals Corp., Novartis Corp. and Novartis International AG related to letrozole tablets, the generic version of Novartis' Femara®. Under the agreement, Mylan is provided a patent license that will enable the Company to market letrozole tablets, 2.5 mg, prior to the expiration of U.S. Patent No. 4,978,672. Additional terms related to the settlement remain confidential, and the agreement is subject to review by the U.S. Department of Justice and the Federal Trade Commission. Letrozole tablets, which are used in the treatment of breast cancer, had U.S. sales of

approximately \$470.0 million for the 12 months ended September 30, 2008, according to IMS. Mylan was the first generic drug company to file a substantially complete ANDA containing a Paragraph IV certification for the product.

**Table of Contents**

**Financial Summary**

Mylan's financial results for calendar year 2008 included total revenues of \$5.14 billion. For the comparable twelve-month period, total revenues were \$2.67 billion. This represents an increase of \$2.47 billion in total revenues. Consolidated gross profit for the current year was \$2.07 billion compared to \$1.11 billion in the comparable twelve-month period, an increase of \$960.9 million. In the current year, operating income of \$297.9 million was realized compared to an operating loss of \$996.1 million in the comparable twelve-month period.

The net loss available to common shareholders for the current year was \$320.3 million compared to \$1.23 billion in the comparable twelve-month period. This translates into a loss per diluted share of \$1.05 for calendar year 2008, compared to \$4.91 in the comparable twelve-month period. Comparability of results between these two periods is affected by the following items:

*Calendar Year 2008:*

The recognition of \$468.1 million (pre-tax) of deferred revenue related to Mylan's sale of the product rights of Bystolic;

\$415.6 million (pre-tax), which consisted 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;

Non-cash impairment loss on the goodwill of the Specialty Segment of \$385.0 million (pre-tax and after-tax);

Non-cash impairment charges of \$72.5 million (pre-tax) on certain other assets;

A \$139.0 million (pre-tax and after-tax) dividend on the 6.5% mandatory convertible preferred stock; and

A full twelve months of results from the former Merck Generics business in calendar year 2008 as compared to three months in calendar year 2007.

*Calendar Year 2007:*

The write-off of acquired in-process research and development related to the acquisition of the former Merck Generics business in the amount of \$1.27 billion (pre-tax and after-tax);

The write-off of acquired in-process research and development related to the acquisition of Matrix of \$147.0 million (pre-tax and after-tax);

Charges totaling \$57.2 million (pre-tax) related to early repayment of certain debt and financing fees;

Net gains of \$85.0 million (pre-tax) on foreign currency exchange contracts, primarily a foreign currency option contract related to the purchase price for the former Merck Generics business acquisition;

\$170.8 million (pre-tax), which consisted primarily of incremental amortization expense related to purchased intangible assets and the amortization of the inventory step-up associated with the acquisitions of the former Merck Generics business and Matrix; and

A \$16.0 million (pre-tax and after-tax) dividend on the 6.5% mandatory convertible preferred stock.

In addition to the above, the loss per common share for calendar year 2007 was impacted by the issuance of 26.2 million shares of common stock in March 2007 and the issuance of 55.4 million shares of common stock in November 2007. Because these offerings occurred during calendar year 2007, the loss per common share did not bear the full impact of these new shares. However, these shares were outstanding for the full calendar year 2008. A more detailed discussion of the Company's financial results can be found below in the section titled Results of Operations .



**Table of Contents****Results of Operations**

	Calendar Year December 31,		Nine Months December 31,		Fiscal Year March 31, 2007
	2008	2007 (Unaudited)	2007	2006 (Unaudited)	
	(In thousands, except per share amounts)				
Revenues:					
Net revenues	\$ 4,631,237	\$ 2,646,643	\$ 2,162,943	\$ 1,103,247	\$ 1,586,947
Other revenues	506,348	19,380	15,818	21,310	24,872
Total revenues	5,137,585	2,666,023	2,178,761	1,124,557	1,611,819
Cost of sales	3,067,364	1,556,728	1,304,313	515,736	768,151
Gross profit	2,070,221	1,109,295	874,448	608,821	843,668
Operating expenses:					
Research and development	317,217	182,911	146,063	66,844	103,692
Acquired in-process research and development		1,416,036	1,269,036		147,000
Goodwill impairment	385,000				
Selling, general and administrative	1,053,485	512,352	449,598	152,784	215,538
Litigation settlements, net	16,634	(5,946)	(1,984)	(46,154)	(50,116)
Total operating expenses	1,772,336	2,105,353	1,862,713	173,474	416,114
Earnings (loss) from operations	297,885	(996,058)	(988,265)	435,347	427,554
Interest expense	357,045	200,394	179,410	31,292	52,276
Other income, net	11,337	97,060	86,611	39,785	50,234
(Loss) earnings before income taxes and minority interest	(47,823)	(1,099,392)	(1,081,064)	443,840	425,512
Income tax provision	137,423	112,823	60,073	155,267	208,017
(Loss) earnings before minority interest	(185,246)	(1,212,215)	(1,141,137)	288,573	217,495
Minority interest (income) expense	(4,031)	(2,901)	(3,112)		211
Net (loss) earnings before preferred dividends	(181,215)	(1,209,314)	(1,138,025)	288,573	217,284
Preferred dividends	139,035	15,999	15,999		

Edgar Filing: MYLAN INC. - Form 10-K

Net (loss) earnings available to common shareholders	\$ (320,250)	\$ (1,225,313)	\$ (1,154,024)	\$ 288,573	\$ 217,284
(Loss) earnings per common share:					
Basic	\$ (1.05)	\$ (4.91)	\$ (4.49)	\$ 1.37	\$ 1.01
Diluted	\$ (1.05)	\$ (4.91)	\$ (4.49)	\$ 1.34	\$ 0.99
Weighted average common shares outstanding:					
Basic	304,360	249,652	257,150	211,075	215,096
Diluted	304,360	249,652	257,150	215,275	219,120

**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

**Table of Contents**

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, which includes approximately 1.0% of unfavorable foreign currency translation impact on Matrix's revenues due to the strengthening of the U.S. Dollar. Matrix contributed third-party revenues of \$376.0 million compared to \$343.6 million in 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 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 \$3.91 billion compared to \$2.22 billion in calendar year 2007. Foreign currency translation had a negative impact on total revenues of approximately 2%, mainly due to the strengthening of the U.S. dollar in comparison to the Euro and Australian dollar. Total revenues from North America were \$1.85 billion for calendar year 2008 compared to \$1.68 billion for calendar year 2007, representing an increase of \$176.6 million. Excluding revenue contributed from the acquisition of Merck Generics 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<sup>®</sup>, 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 the Company expects 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 the Company's 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

## **Table of Contents**

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 \$1.52 billion for calendar year 2008 compared to \$373.1 million for calendar year 2007, all of which were the result of the acquisition of the former Merck Generics business in both periods. Within EMEA, approximately 70% of net revenues are derived from the three largest markets: France, the U.K. and Germany.

Total revenues from Asia Pacific were \$537.4 million for calendar year 2008 compared to \$170.9 million for calendar year 2007, all of which were the result of the acquisition of the former Merck Generics business in both periods. The majority of revenues from Asia Pacific are contributed by Alphapharm, Mylan's Australian subsidiary, with the remainder comprised of sales in Japan and New Zealand.

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. 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.

For calendar year 2008, segment profitability for the Generics Segment was \$969.9 million compared to \$782.1 million in calendar year 2007. Excluding the results of the Merck Generics business from both years segment profitability increased by \$41.3 million. This increase is the result of higher revenues and gross profit, as discussed above, partially offset by increased R&D expense, as further explained below.

### **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 and profitability is EpiPen<sup>®</sup>, an epinephrine auto-injector, which is used in the treatment of severe allergies. EpiPen is the number one prescribed treatment for severe allergic reactions with a U.S. market share of over 95%.

Segment profitability for the Specialty Segment for calendar year 2008 was \$36.6 million compared to \$18.9 million in calendar year 2007.

### **Matrix Segment**

For calendar year 2008, the Matrix Segment reported total revenues of \$444.8 million, of which \$376.0 million represented third-party sales, compared to total revenues of \$389.6 million for calendar year 2007, of which \$343.6 million represented third-party sales. Approximately 50% of the Matrix Segment's third-party net revenues comes from the sale of API and intermediates and approximately 20% comes from the distribution of branded generic products in Europe. The majority of the remainder comes from the sale of Matrix's finished dosage form ( FDF ) anti-retroviral ( ARV ) products. Matrix launched its FDF business in late calendar year 2007. The increase in third-party revenues contributed by Matrix in calendar year 2008 includes approximately 5.0% unfavorable foreign currency impact as a result of the U.S. Dollar strengthening against both the Indian Rupee and the Euro.

**Table of Contents**

In addition to its net revenue, Matrix realized other revenue of \$44.9 million through intersegment product development agreements. Intersegment net revenue consists of API sales to the Generics Segment primarily in conjunction with Mylan's vertical integration strategy.

Segment profitability for the Matrix Segment for calendar year 2008 was \$25.0 million compared to \$26.7 million in calendar year 2007. The decrease in segment profitability is the result of higher operating expenses, as further explained below, partially offset by increased sales and gross profit.

*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, the Company 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 Matrix 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 Matrix 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, the Company 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 \$357.0 million compared to \$200.4 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.

*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 the Company's 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.



**Table of Contents***Income Tax Expense*

For calendar year 2008, income tax expense was \$137.4 million as compared to \$112.8 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 Matrix Segment, and are incremental in the current year. 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<sup>®</sup>, 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 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 \$1.81 billion. Generics Segment revenues are derived from sales primarily in the U.S. and Canada (collectively, North America), Europe, the

**Table of Contents**

Middle East and Africa (collectively, EMEA ) and Australia, Japan and New Zealand (collectively, Asia Pacific ).

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 approximately 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 \$373.1 million for the transition period, all of which were the result of the acquisition of the former Merck Generics business. Within EMEA, approximately 70% of net revenues are derived from the three largest markets; France, the United Kingdom ( U.K. ) and Germany.

In France, where Mylan S.A.S remains the market leader, revenues for the transition period were augmented by the launch of several first-to-market products.

The opposite was observed in the UK where wholesalers decreased their orders to benefit from declining prices driven by intense competition and oversupply. In Germany, the results for the transition period were bolstered by the successful participation in health insurer contracts which were implemented by the German government in April of 2007. Mylan's German subsidiary, Mylan dura, has secured contracts covering approximately 70% of all insured individuals.

Revenues from Asia Pacific were \$170.9 million for the transition period, all of which were the result of the acquisition of the former Merck Generics business. The majority of revenues from Asia Pacific are contributed by Alphapharm, Mylan's Australian subsidiary, with the remainder comprised of sales in Japan, New Zealand and India.

Alphapharm generated strong results due in part to a strategic partnership entered into in October 2007 with one of Australia's leading wholesalers and distributors. Additionally, transition period revenues were bolstered by the launch of several new products.

Japan also produced strong results, which is reflective of the overall growth of the generics sector in that country. Beginning in April of 2008, Japanese pharmacists are able to substitute a generic product for its branded counterpart unless such substitution is blocked by the physician. This program is expected to lead to growth in the rate of generic utilization, for which the government has set a goal of 30% by 2012. However, as measures are put in place to increase generic utilization, increased competition from brand companies is expected. Brand companies are increasingly offering higher discounts in order to maintain market share against generics.

For the transition period, the segment profitability for the Generics Segment was \$590.4 million compared to \$510.0 million in the comparable nine-month period, an increase of \$80.4 million or 16%. Of this increase approximately \$64.5 million is due to the acquisition of the former Merck Generics business. Excluding this amount, segment profitability increased by \$15.9 million due to higher revenues, as discussed above, partially offset by increased spending for R&D as we increased our ANDA submission activity.

## **Table of Contents**

### **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 L.P. ( 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.

DuoNeb is a nebulized unit dose formulation of ipratropium bromide and albuterol sulfate for treatment of chronic obstructive pulmonary disorder ( COPD ). 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, which is used in the treatment of severe allergies, is an epinephrine auto-injector. EpiPen is the number one prescribed treatment for severe allergic reactions with a U.S. market share of over 95%. Prescriptions for EpiPen have continued to grow and during the quarter ended December 31, 2007, have reached the highest prescription volume in the history of the brand.

Segment profitability for the Specialty Segment for the transition period was \$18.9 million, due to the acquisition of the former Merck Generics business.

### **Matrix Segment**

For the transition period, the Matrix Segment reported total revenues of \$293.8 million, of which \$264.2 million represented third-party sales. Approximately 67% of the Matrix Segment's third-party net revenues come from the sale of API and intermediates and approximately 27% mainly from the distribution of branded generic products in Europe. Intersegment revenue was derived from API sales to the Generics Segment primarily in conjunction with Mylan's vertical integration strategy, as well as revenue earned through intersegment product development agreements.

Segment profitability for the Matrix Segment for the transition period was \$18.1 million, due to the acquisition of the former Merck Generics business.

### **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, the Company 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.

## **Table of Contents**

### *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 \$179.4 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, in accordance with SFAS No. 133, *Accounting for Derivative Instruments and Hedging Activities, as amended* ( SFAS No. 133 ), the settlement of this contract was included in current earnings.

The \$57.2 million loss relates to a tender offer made to holders of the Company's 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, the Company 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.

### *Income Tax Expense*

The Company's provision for income taxes was \$60.1 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 (5.6%) as compared to 35.0% for the comparable nine-month period in 2006.

## **Fiscal 2007 Overview**

### *Total Revenues and Gross Profit*

Total revenues for fiscal 2007 were \$1.61 billion. Generics Segment total revenues were \$1.53 billion, and Matrix Segment total revenues were \$79.4 million. For the Generics Segment, net revenues increased over the prior year primarily as a result of increased volume and contribution from new products. Pricing was relatively stable compared to the prior year. New products in fiscal 2007 contributed net revenues of \$108.7 million primarily due to oxybutynin, which was launched in the third quarter.

Excluding new products, fentanyl, which was the only ANDA-approved, AB-rated generic alternative to Duragesic on the market, was a primary driver of both the increased volume and relatively stable pricing. Fentanyl



## **Table of Contents**

accounted for approximately 18% of Generics Segment net revenues for fiscal 2007. For the Generics Segment, doses shipped during fiscal 2007 increased over 12% from the same prior year period to approximately 14.1 billion.

Other revenues for the Generics Segment in fiscal 2007 were \$24.9 million, primarily related to the recognition of amounts that had been deferred with respect to Apokyn, which was sold in the prior year, with the remainder related to other business development activities.

Net revenues for the Matrix Segment were \$95.8 million, of which \$79.4 million were sold to third parties. Mylan began consolidating the results of Matrix on January 8, 2007. Approximately 50% of the Matrix Segment's third-party revenues come from the sale of API and intermediates and approximately 27% is generated mainly from the distribution of branded generic products in Europe. Intercompany revenue was derived from API sales to the Generics Segment primarily in conjunction with the launch of amlodipine which is a vertically integrated product, as well as revenue earned through intercompany product development agreements.

Consolidated gross profit for fiscal 2007 was \$843.7 million, and gross margins were 52.3%. For the Generics Segment, gross profit was \$846.6 million, while gross margins were 55.2%. For the Matrix Segment gross profit was negatively impacted by approximately \$17.6 million representing the reduction of the fair value step-up in inventory, intangible assets and property, plant and equipment recorded as part of the acquisition.

For the Generics Segment, a significant portion of gross profit, as well as the increase in gross margins, was comprised of fentanyl and oxybutynin. Fentanyl contributes margins well in excess of most other products in our portfolio, excluding new products. Absent any changes to market dynamics or significant new competition for fentanyl, the Company expects the product to continue to be a significant contributor to sales and gross profit. Products generally contribute most significantly to gross margin at the time of their launch and, as is the case with oxybutynin, even more so in periods of market exclusivity. As is typical in the generics industry, the entrance into the market of other generic competition generally has a negative impact on the volume and pricing of the affected products.

### *Operating Expenses*

Consolidated R&D expense for fiscal 2007 was \$103.7 million. Matrix Segment R&D expense was \$12.7 million for fiscal 2007 and Generics Segment R&D expense was \$81.8 million.

Additionally, during the fourth quarter of fiscal 2007, the Company recognized a charge of \$147.0 million to write off acquired in-process R&D associated with the Matrix 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.

SG&A expense for fiscal 2007 was \$215.5 million. Generics Segment SG&A expense was \$65.4 million. SG&A expense decreased primarily due to approximately \$20.0 million of cost savings realized from the closure of Mylan Bertek, the Company's branded subsidiary, in the prior year. Partially offsetting this decrease was an increase of approximately \$4.5 million in stock-based compensation expense. Corporate and Other SG&A expense was \$144.4 million in fiscal 2007. The closure of Mylan Bertek in the prior year accounts for the majority of the decrease realized in fiscal 2007. Partially offsetting this were increases in other general and administrative costs, including stock-based compensation expense of approximately \$7.7 million. For Matrix, SG&A expense was \$5.8 million in fiscal 2007.

### *Litigation, net*

Net favorable settlements of \$50.1 million were recorded in fiscal 2007.

*Interest Expense*

Interest expense for fiscal 2007 totaled \$52.3 million. Included in fiscal 2007 interest expense is interest related to the debt assumed in the Matrix acquisition as well as additional debt borrowed to fund the Matrix acquisition, the convertible notes issued in March of 2007, a commitment fee on the revolving credit facilities and the amortization of debt issuance costs.

## **Table of Contents**

### *Other Income, net*

Other income, net was \$50.2 million for fiscal 2007 and includes a \$16.2 million net gain on a foreign currency forward contract related to the acquisition of Matrix. Additionally, during fiscal 2007, the Company received a cash payment of \$5.5 million from an equity method investee.

### **Liquidity and Capital Resources**

Cash flows from operating activities were \$384.4 million for calendar year 2008, consisting primarily of net income (after adding back the non-cash depreciation and amortization expense and the non-cash impairment of \$457.5 million), offset by changes in deferred revenue, accounts receivable, net, and deferred taxes of \$193.6 million.

The change in deferred revenue is driven by the recognition of previously deferred amounts related to the sale of Bystolic rights, and the increase in accounts receivable, net, is the result of increased sales and the timing of cash collections from our customers.

Cash used in investing activities was \$152.8 million for calendar year 2008. Net sales of investments in available-for-sale securities, which consist of a variety of high-credit quality debt securities, including U.S. government, state and local government and corporate obligations, generated a net \$47.7 million in cash. These investments are highly liquid and available for working capital and other needs. As these instruments mature, the funds are generally reinvested in instruments with similar characteristics.

Capital expenditures during calendar year 2008 were \$165.1 million. These expenditures were incurred primarily for equipment, including the Company's previously announced planned expansions and integration plans with respect to the former Merck Generics business acquisition. Also included in investing activities was a cash outflow of \$40.0 million to secure a surety bond with respect to the Company's lorazepam and clorazepate litigation.

Cash used in financing activities was \$166.9 million for calendar year 2008. Cash dividends of \$137.5 million were paid on the Company's 6.5% mandatory convertible preferred stock. In September of 2008, Mylan issued \$575.0 million in Cash Convertible Notes, which accounts for the majority of our total proceeds from long term debt of \$581.4 million. In conjunction with this offering, the Company entered into a convertible note hedge and warrant transaction that resulted in a net outflow of \$98.6 million. The majority of the remaining proceeds following the hedge and warrant transactions were used to repay outstanding indebtedness. In total, debt repayments of \$524.5 million were made during calendar year 2008.

The convertible note hedge and warrant transactions were entered into between the Company and certain counterparties. The cash convertible note hedge is comprised of purchased cash-settled call options. The sale of the warrants resulted in cash proceeds of \$62.6 million which was used along with the proceeds from the issuance of the Cash Convertible Notes, to purchase the bond hedge for approximately \$161.2 million. Subject to the conversion provisions outlined in the Cash Convertible Notes Purchase Agreement, the Cash Convertible Notes have an initial conversion reference rate of 75.0751 shares of common stock per \$1,000 principal amount (equivalent to an initial conversion reference price of \$13.32 per share), subject to adjustment, with the principal amount and remainder payable in cash. The Cash Convertible Notes are not convertible into our common stock or any other securities under any circumstance.

The Company is 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 the Company's 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.

The Company's Consolidated Balance Sheet as of December 31, 2008, includes a \$67.0 million restructuring reserve, which relates to certain estimated exit costs associated with the acquisition of the former Merck Generics

**Table of Contents**

business. The plans related to these exit activities have now been finalized. Payments of approximately \$9.4 million were made during the calendar year ended December 31, 2008, of which \$6.1 million were severance costs and the remaining \$3.3 million were other exit costs.

In September 2008, following the completion of the comprehensive review of strategic alternatives for Dey, the Company announced its decision to retain the Dey business. This decision included a plan to realign the business, including positioning the Company to divest Dey's current facilities over the next two years. As a result, the Company expects to incur certain related exit costs, including related to the realignment of the Dey business. In accordance with the provisions of SFAS No. 146, *Accounting for Costs Associated with Exit or Disposal Activities* (SFAS No. 146), the Company has recorded a reserve of which approximately \$8.0 million remains at December 31, 2008 and made payments of approximately \$0.7 million. In addition, the Company recorded approximately \$3.7 million for the acceleration of depreciation expense during the calendar year ended December 31, 2008. As finalization of the plans are still in progress, the Company has not yet estimated the total amount expected to be incurred in connection with such activities. However, Mylan expects the majority of such costs will relate to one-time termination benefits and certain asset write-downs and could be significant.

The Company is actively pursuing, and is 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 the Company 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.

The Company is continuously evaluating the potential acquisition of products, as well as companies, as a strategic part of its future growth. Consequently, the Company 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, the Company reviews its operations including the evaluation of potential divestitures of products and businesses as part of our future strategy. Any divestitures could impact future liquidity.

Mandatory minimum repayments remaining on the outstanding borrowings under the term loans and convertible notes at December 31, 2008 are as follows for each of the periods ending December 31 below:

	<b>U.S. Tranche A Term Loans</b>	<b>Euro Tranche A Term Loans</b>	<b>U.S. Tranche B Term Loans</b>	<b>Euro Tranche B Term Loans</b>	<b>Senior Convertible Notes</b>	<b>Cash Convertible Notes</b>	<b>Total</b>
<i>(In thousands)</i>							
2009	\$	\$	\$	\$	\$	\$	\$
2010	46,875	73,003	25,560	7,292			152,730
2011	62,500	97,338	25,560	7,292			192,690
2012	78,125	121,672	25,560	7,292	600,000		832,649
2013	78,125	121,671	25,560	7,292			232,648
2014			2,402,640	685,415			3,088,055
Thereafter						655,442	655,442
<b>Total</b>	<b>\$ 265,625</b>	<b>\$ 413,684</b>	<b>\$ 2,504,880</b>	<b>\$ 714,583</b>	<b>\$ 600,000</b>	<b>\$ 655,442</b>	<b>\$ 5,154,214</b>

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. These financial covenants were not

**Table of Contents**

required to be tested earlier than the quarter ended June 30, 2008. The Company has been compliant with the financial covenants during the calendar year ended December 31, 2008.

**Contractual Obligations**

The following table summarizes our contractual obligations at December 31, 2008 and the effect that such obligations are expected to have on our liquidity and cash flows in future periods:

<i>(in thousands)</i>	<b>Total</b>	<b>Less than One Year</b>	<b>One-Three Years</b>	<b>Three-Five Years</b>	<b>Thereafter</b>
Operating leases	\$ 154,336	\$ 30,081	\$ 43,408	\$ 22,942	\$ 57,905
Total debt	5,168,800	3,381	354,290	1,067,449	3,743,680
Scheduled interest payments	1,187,199	237,246	454,980	392,610	102,363
Preferred dividends	278,070	139,035	139,035		
	<b>\$ 6,788,405</b>	<b>\$ 409,743</b>	<b>\$ 991,713</b>	<b>\$ 1,483,001</b>	<b>\$ 3,903,948</b>

The chart above does not include (i) short-term borrowings held by Matrix in the amount of approximately \$151.1 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% - 14%; and (ii) due to the uncertainty with respect to the timing of future cash flows associated with Company's unrecognized tax benefits at December 31, 2008, the Company is unable to make reasonably reliable estimates of the period of cash settlement with the respective taxing authority. Therefore, \$166.5 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 \$265.6 million, the Euro Tranche A Term Loans of \$297.9 (\$413.7) million, the U.S. Tranche B Term Loans of \$2.50 billion, the Euro Tranche B Term Loans of \$514.5 (\$714.6) million, \$600.0 million in Senior Convertible Notes, \$655.4 million in Cash Convertible Notes and \$14.6 million of other miscellaneous debt.

At December 31, 2008, the \$655.4 million of debt related to the Cash Convertible Notes consists of \$419.7 million of debt (\$575.0 million face amount, net of \$155.3 million discount) and a liability with a fair value of \$235.8 million related to the bifurcated conversion feature. The purchased call options are assets recorded at their fair value of \$235.8 million within other assets in the Consolidated Balance Sheets at December 31, 2008.

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.

At December 31, 2008 and December 31, 2007, the Company has \$83.6 million and \$51.3 million in letters of credit outstanding.

The Company has entered into various product licensing and development agreements. In some of these arrangements, the Company provides 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 \$39.3 million would be paid subsequent to December 31, 2008.

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



**Table of Contents**

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.

**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.

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 \$496.5 million and \$420.4 million at December 31, 2008 and December 31, 2007. Other current liabilities include \$236.3 million and \$301.8 million at December 31, 2008 and December 31, 2007, 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 2008:

<i>(in thousands)</i>	<b>Balance at 12/31/2007</b>	<b>Checks/Credits Issued to Third Parties</b>	<b>Current Provision Related to Sales Made in the Current Period</b>	<b>Effects of Foreign Exchange</b>	<b>Balance at 12/31/2008</b>
Chargebacks	\$ 215,272	\$ (1,485,012)	\$ 1,456,089	\$ (3,537)	\$ 182,812
Promotions and indirect rebates	\$ 302,495	\$ (724,742)	\$ 753,746	\$ (14,285)	\$ 317,214
Returns	\$ 90,689	\$ (73,591)	\$ 66,726	\$ (2,529)	\$ 81,295

The accrual for chargebacks decreased as a result of numerous factors including a decrease in the estimate of the amount of inventory on the shelves of our U.S. wholesale customers, a shift in sales to customers for whom chargebacks are not offered in Germany, and a decrease in Australia in conjunction with the country-wide, government-mandated decrease in generic pharmaceutical pricing. The accrual for promotions and indirect rebates increased primarily due to accruals for new products in the U.S. and an increase in the overall business in markets such as France and Germany, offset by decreases in Canada and the U.K.

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 price adjustments, returns and chargebacks,

**Table of Contents**

require management to make more subjective judgments and evaluate current market conditions. These provisions are discussed in further detail below.

*Price Adjustments* Price adjustments, which include shelf stock adjustments, are credits issued to reflect decreases in the selling prices of our products. Shelf stock adjustments are based upon the amount of product that our customers have remaining in their inventories at the time of the price reduction. Decreases in our selling prices and the issuance of credits are discretionary decisions made by us to reflect market conditions. Amounts recorded for estimated price adjustments are based upon specified terms with direct customers, estimated launch dates of competing products, estimated declines in market price and, in the case of shelf stock adjustments, estimates of inventory held by the customer. In most cases, data with respect to the level of inventory held by the customer is obtained directly from certain of our largest customers. Additionally, internal estimates are prepared based upon historical buying patterns and estimated end-user demand. Such information allows us to assess the impact that a price adjustment will have given the quantity of inventory on hand. We regularly monitor these and other factors and evaluate our reserves and estimates as additional information becomes available. A variance of 5% between estimated and actual inventory levels would have an effect on our reserve balance of approximately \$3.0 million.

*Returns* Consistent with industry practice, we maintain a return policy that allows our customers to return product within a specified period prior to and subsequent to the expiration date. 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. 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. 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 \$4.0 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 \$8.0 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

## **Table of Contents**

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, including transaction costs, 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 have been expensed at the date of acquisition. Intangible assets are amortized over the expected life of the asset. Any excess of the purchase price over the estimated fair values of the net assets acquired is recorded as goodwill.

The judgments made in determining the estimated fair value assigned to each class of assets acquired and liabilities assumed, as well as asset lives, can materially impact our results of operations. Fair values and useful lives are determined based on, among other factors, the expected future period of benefit of the asset, the various characteristics of the asset and projected cash flows. Because this process involves management making estimates with respect to future sales volumes, pricing, new product launches, 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 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 FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes – an Interpretation of FASB Statement 109* (FIN 48). FIN 48 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.

**Table of Contents**

The resolution of tax reserves and changes in valuation allowances could be material to the Company's results of operations or financial position.

*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.

**Recent Accounting Pronouncements**

In June 2008, the Financial Accounting Standards Board ( FASB ) issued FASB Staff Position ( FSP ) No. EITF 03-6-1, *Determining Whether Instruments Granted in Share-Based Payment Transactions Are Participating Securities* ( FSP No. EITF 03-6-1 ). FSP No. EITF 03-6-1 states that unvested share-based payment awards that contain nonforfeitable rights to dividends or dividend equivalents (whether paid or unpaid) are participating securities and shall be included in the computation of earnings per share pursuant to the two-class method. FSP No. EITF 03-6-1 is effective for fiscal years beginning after December 15, 2008. The adoption of FSP No. EITF 03-6-01 will not have an impact on the Company's Consolidated Financial Statements.

In May 2008, the FASB issued FSP No. APB 14-1, *Accounting for Convertible Debt Instruments That May Be Settled in Cash Upon Conversion (Including Partial Cash Settlement)* ( FSP No. APB 14-1 ). Under the new rules for convertible debt instruments (including our Senior Convertible Notes) that may be settled entirely or partially in cash upon conversion, an entity should 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 for the debentures is that the equity component would be included in the paid-in-capital section of stockholders' equity on our consolidated balance sheet and the value of the equity component would be treated as original issue discount for purposes of accounting for the debt component of the Senior Convertible Notes. FSP No. APB 14-1 will be effective for fiscal years beginning after December 15, 2008, and for interim periods within those fiscal years, with retrospective application required. Higher interest expense will result through the accretion of the discounted carrying value of the Senior Convertible Notes to their face amount over the term of the Senior Convertible Notes. Prior period interest expense will also be higher than previously reported interest expense due to retrospective application. Early adoption is not permitted. The Company has evaluated the impact of adopting FSP No. APB 14-1 on its Consolidated Financial Statements and determined that the retrospective application will increase the net loss available to common shareholders by approximately \$10.0 million for the nine months ended December 31, 2007, and \$15.0 million for calendar year ended December 31, 2008. In addition, at December 31, 2008, additional paid-in capital will increase by \$85.0 million and long-term debt, retained earnings and tax assets will decrease by \$87.0 million, \$26.0 million and \$28.0 million, respectively.

In April 2008, the FASB issued FSP No. FAS 142-3, *Determination of the Useful Life of Intangible Assets* ( FSP No. FAS 142-3 ). FSP No. FAS 142-3 amends the factors that should be considered in developing renewal or extension assumptions used to determine the useful life of a recognized intangible asset under SFAS No. 142, in order to improve the consistency between the useful life of a recognized intangible asset under SFAS No. 142 and the period of expected cash flows used to measure the fair value of the asset under SFAS No. 141(R), *Business Combinations* ( SFAS No. 141(R) ) and other accounting principles generally accepted in the United States of America ( GAAP ). FSP No. FAS 142-3 is effective for fiscal years beginning after December 15, 2008. The adoption of FSP No. FAS 142-3 will not have a material impact on the Company's Consolidated Financial Statements.

In March 2008, the FASB issued SFAS No. 161, *Disclosures about Derivative Instruments and Hedging Activities* an amendment of FASB Statement No. 133 ( SFAS No. 161 ). SFAS No. 161 requires enhanced disclosures about an entity s derivative and hedging activities, including (i) how and why an entity uses derivative instruments, (ii) how derivative instruments and related hedged items are accounted for under SFAS No. 133, and



**Table of Contents**

(iii) how derivative instruments and related hedged items affect an entity's financial position, financial performance, and cash flows. This standard is effective for fiscal years beginning after November 15, 2008. Management is currently assessing the impact of the disclosures on the Company's Consolidated Financial Statements.

In March 2008, the Emerging Issues Task Force (EITF) issued EITF No. 07-5, *Determining Whether an Instrument (or Embedded Feature) is Indexed to an Entity's Own Stock* (EITF No. 07-5). EITF No. 07-5 states that if an instrument (or an embedded feature) has the characteristics of a derivative instrument under paragraphs 6-9 of SFAS No. 133, and is indexed to an entity's own stock, it is necessary to evaluate whether it is classified in shareholders' equity (or would be classified in stockholders' equity if it were a freestanding instrument). EITF No. 07-5 is effective for fiscal years beginning after December 15, 2008. The adoption of EITF No. 07-5 will not have a material impact on the Company's Consolidated Financial Statements.

On January 1, 2008, the Company adopted SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities – including an amendment of FASB Statement No. 115* (SFAS No. 159). SFAS No. 159 permits entities to choose to measure many financial instruments and certain other assets and liabilities at fair value on an instrument-by-instrument basis (the fair value option) with changes in fair value reported in earnings. The Company already records marketable securities at fair value in accordance with SFAS No. 115, *Accounting for Certain Investments in Debt and Equity Securities* (SFAS No. 115), and derivative contracts and hedging activities at fair value in accordance with SFAS No. 133. The adoption of SFAS No. 159 did not have a material impact on the Company's Consolidated Financial Statements as management did not elect the fair value option for any other financial instruments or certain other assets and liabilities.

On January 1, 2008, the Company adopted Statement 133 Implementation Issue No. E23, *Hedging – General: Issues Involving the Application of the Shortcut Method under Paragraph 58* (Issue No. E23). Issue No. E23 provides guidance on certain practice issues related to the application of the shortcut method by amending paragraph 68 of SFAS No. 133 with respect to the conditions that must be met in order to apply the shortcut method for assessing hedge effectiveness of interest rate swaps. In addition to applying the provisions of Issue No. E23 on hedging arrangements designated on or after January 1, 2008, an assessment was required to be made on January 1, 2008 to determine whether preexisting hedging arrangements met the provisions of Issue No. E23 as of their original inception. Management performed such an assessment and determined that the adoption of Issue No. E23 did not have a material impact on preexisting hedging arrangements.

In December 2007, the FASB issued SFAS No. 141(R). SFAS No. 141(R) replaces SFAS No. 141, *Business Combinations*, (SFAS No. 141) and retains the fundamental requirements in SFAS No. 141, including that the purchase method be used for all business combinations and for an acquirer to be identified for each business combination. This standard defines the acquirer as the entity that obtains control of one or more businesses in the business combination and establishes the acquisition date as the date that the acquirer achieves control instead of the date that the consideration is transferred. SFAS No. 141(R) requires an acquirer in a business combination, including business combinations achieved in stages (step acquisition), to recognize the assets acquired, liabilities assumed, and any noncontrolling interest in the acquiree at the acquisition date, measured at their fair values at that date, with limited exceptions. It also requires the recognition of assets acquired and liabilities assumed arising from certain contractual contingencies as of the acquisition date, measured at their acquisition-date fair values. SFAS No. 141(R) is effective for any business combination with an acquisition date on or after January 1, 2009. The Company is currently evaluating the potential impact of SFAS No. 141(R) on the Consolidated Financial Statements.

In December 2007, the FASB issued SFAS No. 160, *Noncontrolling Interests in Consolidated Financial Statements – an amendment of ARB No. 51* (SFAS No. 160). SFAS No. 160 amends Accounting Research Bulletin No. 51, *Consolidated Financial Statements*, 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. SFAS No. 160 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

**Table of Contents**

former subsidiary be measured at fair value and a gain or loss be recognized in net income based on such fair value. SFAS No. 160 is effective for fiscal years beginning after December 15, 2008. Although certain captions and disclosures will be revised, the adoption of SFAS No. 160 will not have a material impact on the Company's Consolidated Financial Statements.

In March 2007, the EITF issued EITF No. 06-10, *Accounting for Collateral Assignment Split-Dollar Life Insurance Arrangements* ( EITF No. 06-10 ). Under the provisions of EITF No. 06-10, an employer is required to recognize a liability for the postretirement benefit related to a collateral assignment split-dollar life insurance arrangement with the employee. The provisions of EITF No. 06-10 also require an employer to recognize and measure the asset in a collateral assignment split-dollar life insurance arrangement based on the nature and substance of the arrangement. The Company adopted the provisions of EITF No. 06-10 as of January 1, 2008. As a result of the adoption, the Company recognized a liability of \$8.3 million, representing the present value of the future premium payments to be made under the existing policies. In accordance with the transition provisions of EITF No. 06-10, this amount was recorded as a direct decrease to retained earnings.

In March 2007, the EITF issued EITF No. 06-04, *Accounting for Deferred Compensation and Postretirement Benefit Aspects of Endorsed Split-Dollar Life Insurance Arrangements* ( EITF No. 06-4 ), which concludes that an employer should recognize a liability for post-employment benefits promised an employee based on the substantive arrangement between the employer and the employee. The Company adopted the provisions of EITF No. 06-04 as of January 1, 2008. The adoption of EITF No. 06-04 did not have a material impact on the Company's Consolidated Financial Statements.

**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 Company accounted for these instruments under the provisions of SFAS No. 133. The instruments did not qualify for hedge accounting treatment under SFAS No. 133 and therefore were required to be adjusted to fair value with the change in the fair value of the instrument recorded in current earnings.

## **Table of Contents**

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. In 2008, the Company issued \$575.0 million in Cash Convertible Notes with a fixed coupon of 3.75%.

Mylan's long-term borrowings consist principally of \$2.77 billion in U.S. dollar denominated loans and \$1.13 billion in Euro denominated debt under our Senior Credit Agreement, \$600.0 million in Senior Convertible Notes and \$655.4 million in Cash Convertible Notes.

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, 2008, the fair value of our Senior Convertible Notes was approximately \$444.0 million and the fair value of Mylan's Cash Convertible Notes was approximately \$524.4 million. A 10% change in interest rates on the variable rate debt, net of interest rate swaps, would result in a change in interest expense of approximately \$12.0 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, 2008 or 2007. 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, 2008, the Company had invested \$41.7 million in available-for-sale securities, of which \$2.8 million will mature within one year and \$38.9 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 \$38.9 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 \$2.0 million decrease in the fair value of available-for-sale securities.



**Table of Contents**

**ITEM 8. Financial Statements and Supplementary Data**

**Index to Consolidated Financial Statements and  
Supplementary Financial Information**

	<b>Page</b>
<u>Consolidated Balance Sheets as of December 31, 2008 and December 31, 2007</u>	73
<u>Consolidated Statements of Operations for the Calendar Year Ended December 31, 2008, Nine Months Ended December 31, 2007, and Fiscal Year Ended March 31, 2007</u>	74
<u>Consolidated Statements of Shareholders' Equity for the Calendar Year Ended December 31, 2008, Nine Months Ended December 31, 2007, and Fiscal Year Ended March 31, 2007</u>	75
<u>Consolidated Statements of Cash Flows for the Calendar Year Ended December 31, 2008, Nine Months Ended December 31, 2007, and Fiscal Year Ended March 31, 2007</u>	77
<u>Notes to Consolidated Financial Statements</u>	78
<u>Management's Report on Internal Control over Financial Reporting</u>	120
<u>Reports of Independent Registered Public Accounting Firm</u>	121
<u>Supplementary Financial Information</u>	123

**Table of Contents**

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

	<b>December 31, 2008</b>	<b>December 31, 2007</b>
Assets		
Current assets:		
Cash and cash equivalents	\$ 557,147	\$ 484,202
Restricted cash	40,309	
Available-for-sale securities	42,260	91,361
Accounts receivable, net	1,164,613	1,132,121
Inventories	1,065,990	1,063,840
Deferred income tax benefit	199,278	192,113
Prepaid expenses and other current assets	105,076	95,664
Total current assets	3,174,673	3,059,301
Property, plant and equipment, net	1,063,996	1,102,932
Intangible assets, net	2,453,161	2,978,706
Goodwill	3,161,580	3,855,971
Deferred income tax benefit	16,493	18,703
Other assets	539,956	337,563
Total assets	\$ 10,409,859	\$ 11,353,176
Liabilities and shareholders' equity		
Liabilities		
Current liabilities:		
Trade accounts payable	\$ 585,711	\$ 608,070
Short-term borrowings	151,109	144,355
Income taxes payable	92,158	169,518
Current portion of long-term debt and other long-term obligations	5,099	410,934
Deferred income tax liability	1,935	24,344
Other current liabilities	708,638	645,130
Total current liabilities	1,544,650	2,002,351
Deferred revenue	18,021	122,870
Long-term debt	5,165,419	4,706,716
Other long-term obligations	404,031	206,672
Deferred income tax liability	545,121	876,816
Total liabilities	7,677,242	7,915,425
Minority interest	29,108	34,325
Shareholders' equity		
Preferred stock - par value \$0.50 per share		



Edgar Filing: MYLAN INC. - Form 10-K

Shares authorized: 5,000,000 as of December 31, 2008 and 2007		
Shares issued: 2,139,000 as of December 31, 2008 and 2007	1,070	1,070
Common stock par value \$0.50 per share		
Shares authorized: 600,000,000 as of December 31, 2008 and 2007		
Shares issued: 395,368,062 and 395,260,355 as of December 31, 2008 and 2007	197,684	197,630
Additional paid-in capital	3,873,743	3,785,729
Retained earnings	594,352	922,857
Accumulated other comprehensive (loss) earnings	(380,802)	83,044
	4,286,047	4,990,330
Less treasury stock at cost		
Shares: 90,635,441 and 90,885,188 as of December 31, 2008 and 2007	1,582,538	1,586,904
Total shareholders equity	2,703,509	3,403,426
Total liabilities and shareholders equity	\$ 10,409,859	\$ 11,353,176

*See Notes to Consolidated Financial Statements*

**Table of Contents**

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

	<b>Calendar Year Ended December 31, 2008</b>	<b>Nine Months Ended December 31, 2007</b>	<b>Fiscal Year Ended March 31, 2007</b>
Revenues:			
Net revenues	\$ 4,631,237	\$ 2,162,943	\$ 1,586,947
Other revenues	506,348	15,818	24,872
Total revenues	5,137,585	2,178,761	1,611,819
Cost of sales	3,067,364	1,304,313	768,151
Gross profit	2,070,221	874,448	843,668
Operating expenses:			
Research and development	317,217	146,063	103,692
Acquired in-process research and development		1,269,036	147,000
Goodwill impairment	385,000		
Selling, general and administrative	1,053,485	449,598	215,538
Litigation settlements, net	16,634	(1,984)	(50,116)
Total operating expenses	1,772,336	1,862,713	416,114
Earnings (loss) from operations	297,885	(988,265)	427,554
Interest expense	357,045	179,410	52,276
Other income, net	11,337	86,611	50,234
(Loss) earnings before income taxes and minority interest	(47,823)	(1,081,064)	425,512
Income tax provision	137,423	60,073	208,017
(Loss) earnings before minority interest	(185,246)	(1,141,137)	217,495
Minority interest (income) expense	(4,031)	(3,112)	211
Net (loss) earnings before preferred dividends	(181,215)	(1,138,025)	217,284
Preferred dividends	139,035	15,999	
Net (loss) earnings available to common shareholders	\$ (320,250)	\$ (1,154,024)	\$ 217,284
(Loss) earnings per common share:			
Basic	\$ (1.05)	\$ (4.49)	\$ 1.01

Edgar Filing: MYLAN INC. - Form 10-K

Diluted	\$	(1.05)	\$	(4.49)	\$	0.99
Weighted average common shares outstanding:						
Basic		304,360		257,150		215,096
Diluted		304,360		257,150		219,120

*See Notes to Consolidated Financial Statements*

**Table of Contents**

**MYLAN INC. AND SUBSIDIARIES**  
**Consolidated Statements of Shareholders' Equity**  
(in thousands, except share and per share amounts)

Comprehensive Earnings (Loss)	Preferred Stock		Common Stock		Additional Paid-In	Retained	Treasury Stock	
	Shares	Cost	Shares	Cost	Capital	Earnings	Shares	Cost
\$ 217,284		\$	309,150,251	\$ 154,575	\$ 418,954	\$ 1,939,045 217,284	(98,971,431)	\$ (1,7
1,266								
(900)								
366								
217,650								
			26,162,500	13,081	476,015			
			4,048,450	2,025	47,242 45,360			
					(2,526)		(35,665)	
					23,045		8,058,139	1
					(81,900)			
					22,156			
					14,419			
						(53,047)		

				(19)		
		339,361,201	169,681	962,746	2,103,282	(90,948,957) (1,5
\$ (1,138,025)					(1,138,025)	
(663)						
87,602						
(4,723)						
(716)						
81,500						
(1,056,525)						
		55,440,000	27,720	720,331		
		459,154	229	7,503		
	2,139,000	1,070		2,072,816		
				(1,485)		63,769
				17,332		
				5,648		
					(11,478)	
					(15,999)	
					(14,923)	
				838		

2,139,000 \$ 1,070 395,260,355 \$ 197,630 \$ 3,785,729 \$ 922,857 (90,885,188) \$ (1,5

*See Notes to Consolidated Financial Statements*

**Table of Contents**

**MYLAN INC. AND SUBSIDIARIES**  
**Consolidated Statements of Shareholders' Equity (Continued)**  
(in thousands, except share and per share amounts)

Comprehensive Earnings (Loss)	Preferred Stock		Common Stock		Additional Paid-In	Retained	Treasury Stock	
	Shares	Cost	Shares	Cost	Capital	Earnings	Shares	Cost
(181,215)						(181,215)		
(2,529)								
(420,167)								
(40,633)								
(517)								
(463,846)								
(645,061)								
			107,707	54	1,137			
					(5,529)		249,747	4,366
					30,639			
					(223)			
					62,560			

(8,255)

(139,035)

(570)

2,139,000 \$ 1,070 395,368,062 \$ 197,684 \$ 3,873,743 \$ 594,352 (90,635,441) \$ (1,582,53

*See Notes to Consolidated Financial Statements*



**Table of Contents**

**MYLAN INC. AND SUBSIDIARIES**  
**Consolidated Statements of Cash Flows**  
(in thousands)

	<b>Calendar Year Ended December 31, 2008</b>	<b>Nine Months Ended December 31, 2007</b>	<b>Fiscal Year Ended March 31, 2007</b>
Cash flows from operating activities:			
Net (loss) earnings before preferred dividends	\$ (181,215)	\$ (1,138,025)	\$ 217,284
Adjustments to reconcile net (loss) earnings before preferred dividends to net cash provided by operating activities:			
Depreciation and amortization	425,279	157,800	61,512
Stock-based compensation expense	30,639	17,332	22,156
In-process research and development		1,269,036	147,000
Minority interest	(4,031)	(3,112)	211
Net income from equity method investees	(4,161)	(2,573)	(6,659)
Change in estimated sales allowances	10,576	31,337	14,386
Deferred income taxes	(193,564)	(77,131)	(50,479)
Non-cash impairments	457,517		
Other non-cash items	31,076	54,408	7,914
Litigation settlements, net	16,635	(4,526)	6,464
Cash received from Somerset			5,870
Gain on foreign exchange contract		(85,063)	
Changes in operating assets and liabilities:			
Accounts receivable	(172,447)	(124,385)	(60,773)
Inventories	(83,327)	16,305	(28,987)
Trade accounts payable	23,166	86,467	(29,312)
Income taxes	73,983	(34,632)	73,567
Deferred revenue	(113,998)	34,864	(5,504)
Other operating assets and liabilities, net	68,319	(30,413)	15,542
Net cash provided by operating activities	384,447	167,689	390,192
Cash flows from investing activities:			
Capital expenditures	(165,113)	(110,538)	(161,851)
Acquisitions, net of cash acquired		(7,001,930)	(761,049)
Increase in restricted cash	(38,182)		
Purchase of available-for-sale securities	(18,032)	(275,802)	(655,948)
Proceeds from sale of available-for-sale securities	65,712	357,922	848,520
Other items, net	2,785	(4,976)	(407)
Net cash used in investing activities	(152,830)	(7,035,324)	(730,735)
Cash flows from financing activities:			

Edgar Filing: MYLAN INC. - Form 10-K

Cash dividends paid	(137,495)	(29,825)	(50,751)
Payment of financing fees	(15,074)	(89,538)	(15,329)
Proceeds from the issuance of preferred stock, net		2,073,886	
Proceeds from issuance of common stock, net		748,051	657,678
Purchase of bond hedge	(161,173)		(126,000)
Proceeds from issuance of warrants	62,560		45,360
Change in short-term borrowing, net	26,239	26,240	
Proceeds from long-term debt	581,352	7,701,240	1,556,251
Payment of long-term debt	(524,536)	(4,389,183)	(689,938)
Proceeds from exercise of stock options	1,191	7,732	49,824
Change in outstanding checks in excess of cash disbursements accounts		18,008	10,403
Other items, net		2,171	5,318
Net cash (used in) provided by financing activities	(166,936)	6,068,782	1,442,816
Effect on cash and cash equivalents of changes in exchange rates	8,264	30,690	(32)
Net increase (decrease) in cash and cash equivalents	72,945	(768,163)	1,102,241
Cash and cash equivalents beginning of period	484,202	1,252,365	150,124
Cash and cash equivalents end of period	\$ 557,147	\$ 484,202	\$ 1,252,365
Supplemental disclosures of cash flow information:			
Cash paid during the year for:			
Income taxes	\$ 218,012	\$ 179,092	\$ 176,353
Interest	\$ 307,895	\$ 174,034	\$ 59,996

*See Notes to Consolidated Financial Statements*

**Table of Contents****Mylan Inc. and Subsidiaries****Notes to Consolidated Financial Statements****Note 1. Nature of Operations**

Mylan Inc. and its subsidiaries (the Company or Mylan) are engaged in the development, licensing, manufacture, marketing and distribution of generic, brand and branded generic pharmaceutical products for resale by others and active pharmaceutical ingredients (API) globally through three reportable segments in accordance with Statement of Financial Accounting Standards (SFAS) No. 131, *Disclosures about Segments of an Enterprise and Related Information* (SFAS No. 131), the Generics Segment, the Specialty Segment and the Matrix Segment. The principal markets for the Generics Segment products are proprietary and ethical pharmaceutical wholesalers and distributors, drug store chains, drug manufacturers, institutions, and public and governmental agencies primarily within the United States (U.S.) and Canada (collectively, North America), Europe, Middle East and Africa (collectively, EMEA), and Australia, Japan and New Zealand (collectively, Asia Pacific). The Matrix Segment has a wide range of products in multiple therapeutic categories and focuses mainly on developing API with non-infringing processes to partner with generic manufacturers in regulated markets such as the U.S. and the European Union (EU) at market formation. The principal market for the Specialty Segment is also pharmaceutical wholesalers and distributors primarily in the U.S.

The Company amended its articles of incorporation to change its name from Mylan Laboratories Inc. to Mylan Inc., effective as of 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.

**Note 2. Summary of Significant Accounting Policies**

**Principles of Consolidation.** The Consolidated Financial Statements include the accounts of Mylan Inc. and those of its wholly-owned and majority-owned subsidiaries. All intercompany accounts and transactions have been eliminated in consolidation. Non-controlling interests in the Company's subsidiaries are recorded net of tax as minority interest.

On October 2, 2007, Mylan completed its acquisition of Merck KGaA's generics business (the former Merck Generics business). Accordingly, Mylan began consolidating the results of operations of the former Merck Generics business as of October 2, 2007 (see Note 3).

**Cash and Cash Equivalents.** Cash and cash equivalents are comprised of highly liquid investments with an original maturity of three months or less at the date of purchase.

**Available-for-Sale Securities.** Debt and marketable equity securities are classified as available-for-sale and are recorded at fair value, with net unrealized gains and losses, net of income taxes, reflected in accumulated other comprehensive earnings as a component of shareholders' equity. Net realized gains and losses on sales of available-for-sale securities are computed on a specific security basis and are included in other income in the Consolidated Statements of Operations.

**Concentrations of Credit Risk.** Financial instruments that potentially subject the Company to credit risk consist principally of interest-bearing investments, derivatives and accounts receivable.

Mylan invests its excess cash in high-quality, liquid money market instruments, principally overnight deposits, highly rated money market funds and market auction securities. The Company maintains deposit balances at certain financial

institutions in excess of federally insured amounts. Periodically, the Company reviews the creditworthiness of its counterparties to derivative transactions, and it does not expect to incur a loss from failure of any counterparties to perform under agreements it has with such counterparties.

Mylan performs ongoing credit evaluations of its customers and generally does not require collateral. Approximately 37% and 34% of the accounts receivable balances represent amounts due from three customers at December 31, 2008 and December 31, 2007. Total allowances for doubtful accounts were \$26.9 million and \$38.1 million at December 31, 2008 and December 31, 2007.

**Table of Contents**

***Inventories.*** Inventories are stated at the lower of cost or market, with cost determined by the first-in, first-out method. Provisions for potentially obsolete or slow-moving inventory, including pre-launch inventory, are made based on our analysis of inventory levels, historical obsolescence and future sales forecasts.

***Property, Plant and Equipment.*** Property, plant and equipment are stated at cost less accumulated depreciation. Depreciation is computed and recorded on a straight-line basis over the assets' estimated service lives (3 to 19 years for machinery and equipment and 15 to 39 years for buildings and improvements). The Company periodically reviews the original estimated useful lives of assets and makes adjustments when appropriate. Depreciation expense was \$122.8 million, \$57.1 million and \$39.1 million for the calendar year ended December 31, 2008, the nine months ended December 31, 2007 and fiscal year ended March 31, 2007, respectively.

***Intangible Assets and Goodwill.*** Intangible assets are stated at cost less accumulated amortization. Amortization is generally recorded on a straight-line basis over estimated useful lives ranging from 5 to 20 years. The Company periodically reviews the original estimated useful lives of assets and makes adjustments when events indicate that a shorter life is appropriate.

The Company accounts 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 fair values. The cost to acquire a business, including transaction costs, is allocated to the underlying net assets of the acquired business in proportion to their respective fair values. Amounts allocated to acquired in-process research and development are expensed at the date of acquisition. Definite lived intangible assets are amortized over the expected life of the asset. Any excess of the purchase price over the estimated fair values of the net assets acquired is recorded as goodwill.

The judgments made in determining the estimated fair value assigned to each class of assets acquired and liabilities assumed, as well as asset lives, can materially impact the Company's 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.

***Impairment of Long-Lived Assets.*** The carrying values of long-lived assets, which include property, plant and equipment and intangible assets with finite lives, are evaluated periodically in relation to the expected future cash flows of the underlying assets and monitored for other potential triggering events. Adjustments are made in the event that estimated undiscounted net cash flows are less than the carrying value.

Goodwill is tested for impairment at least annually or when events or other changes in circumstances indicate that the carrying amount of the assets may not be recoverable based on management's assessment of the fair value of the Company's identified reporting units as compared to their related carrying value. If the fair value of a reporting unit is less than its carrying value, additional steps, including an allocation of the estimated fair value to the assets and liabilities of the reporting unit, would be necessary to determine the amount, if any, of goodwill impairment.

Indefinite-lived intangibles are tested at least annually for impairment. Impairment is determined to exist when the fair value is less than the carrying value of the assets being tested.

***Other Assets.*** Investments in business entities in which the Company has the ability to exert significant influence over operating and financial policies (generally 20% to 50% ownership) are accounted for using the equity method. Under the equity method, investments are initially recorded at cost and are adjusted for dividends, distributed and undistributed earnings and losses, changes in foreign exchange rates, and additional investments. Other assets are periodically reviewed for other-than-temporary declines in fair value.

**Short-Term Borrowings.** Matrix has a financing arrangement for the sale of its accounts receivable with certain commercial banks. The commercial banks purchase the receivables at a discount and Matrix records the proceeds as short-term borrowings. Upon receipt of payment of the receivable, the short-term borrowings are reversed. As the banks have recourse to Matrix on the receivables sold, the receivables are included in accounts receivable, net in the Consolidated Balance Sheets. Additionally, Matrix has working capital facilities with several banks which are secured first by Matrix's current assets and second by Matrix's property, plant and equipment. The working capital facilities carry interest rates of 4%-14%.

**Table of Contents**

**Revenue Recognition.** Mylan recognizes revenue for product sales when title and risk of loss pass to its customers and when provisions for estimates, including discounts, rebates, price adjustments, returns, chargebacks and other promotional programs, are reasonably determinable. No revisions were made to the methodology used in determining these provisions during the calendar year ended December 31, 2008. The following briefly describes the nature of each provision and how such provisions are estimated.

Discounts are reductions to invoiced amounts offered to customers for payment within a specified period and are estimated upon sale utilizing historical customer payment experience.

Rebates are offered to key customers to promote customer loyalty and encourage greater product sales. These rebate programs provide that upon the attainment of pre-established volumes or the attainment of revenue milestones for a specified period, the customer receives credit against purchases. Other promotional programs are incentive programs periodically offered to our customers. The Company is able to estimate provisions for rebates and other promotional programs based on the specific terms in each agreement at the time of sale.

Consistent with industry practice, Mylan maintains a return policy that allows customers to return product within a specified period prior to and subsequent to the expiration date. The Company's estimate of the provision for returns is generally based upon historical experience with actual returns.

Price adjustments, which include shelf stock adjustments, are credits issued to reflect decreases in the selling prices of products. Shelf stock adjustments are based upon the amount of product which the customer has remaining in its inventory at the time of the price reduction. Decreases in selling prices are discretionary decisions made by the Company to reflect market conditions. Amounts recorded for estimated price adjustments are based upon specified terms with direct customers, estimated launch dates of competing products, estimated declines in market price and, in the case of shelf stock adjustments, estimates of inventory held by the customer.

The Company has agreements with certain indirect customers, such as independent pharmacies, managed care organizations, hospitals, nursing homes, governmental agencies and pharmacy benefit management companies, which establish contract prices for certain products. The indirect customers then independently select a wholesaler from which to actually purchase the products at these contracted prices. 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. 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.

At March 31, 2007, as a result of significant uncertainties surrounding the Food and Drug Administration's (FDA's) approval of additional abbreviated new drug applications (ANDAs) with respect to a product launched by the Company in late March 2007, the Company was not able to reasonably estimate the amount of potential price adjustments that would occur as a result of the additional approvals. As a result, revenues on shipments of this product were deferred until such uncertainties were resolved. Initially, such uncertainties were considered to be resolved upon our customers' sale of this product. During the quarter ended September 30, 2007, as a result of additional competition entering the market upon companies receiving final FDA approval, these uncertainties were resolved and the Company was able to reasonably estimate the amount of potential price adjustments. Accordingly, all revenues on shipments previously deferred were recognized and revenue is currently being recorded as described above.

Accounts receivable are presented net of allowances relating to the above provisions. No revisions were made to the methodology used in determining these provisions during the calendar year ended December 31, 2008 and the nine months ended December 31, 2007. Such allowances were \$496.5 million and \$420.4 million at December 31, 2008 and December 31, 2007. Other current liabilities include \$236.3 million and \$301.8 million at December 31, 2008 and December 31, 2007, for certain rebates and other adjustments that are paid to indirect customers.

The Company periodically enters into various types of revenue arrangements with third-parties, including agreements for the sale or license of product rights or technology, research and development agreements, collaboration agreements and others. These agreements may include the receipt of upfront and milestone payments, royalties, and payment for contract manufacturing and other services.



**Table of Contents**

The Company recognizes all non-refundable payments as revenue in accordance with the guidance provided in the Securities and Exchange Commission ( SEC ) Staff Accounting Bulletin ( SAB ) No. 104, *Revenue Recognition, corrected copy*, and Emerging Issues Task Force ( EITF ) Issue No. 00-21, *Revenue Arrangements with Multiple Deliverables*. Non-refundable fees received upon entering into license and other collaborative agreements where the Company has continuing involvement are recorded as deferred revenue and recognized as other revenue over an appropriate period of time.

Royalty revenue from licensees, which are based on third-party sales of licensed products and technology, is earned in accordance with the contract terms when third-party sales can be reliably measured and collection of the funds is reasonably assured. Royalty revenue is included in other revenue in the Consolidated Statements of Operations.

The Company recognizes contract manufacturing and other service revenue when the service is performed or when the Company's partners take ownership and title has passed, collectability is reasonably assured, the sales price is fixed or determinable and there is persuasive evidence of an arrangement.

During the calendar year ended December 31, 2008, sales to McKesson Corporation and Cardinal Health, Inc. represented 12% and 10% of consolidated net revenues. Sales to Cardinal Health, Inc. and McKesson Corporation represented 11% and 16% of consolidated net revenues during the nine months ended December 31, 2007. Sales to AmerisourceBergen Corporation, Cardinal Health, Inc. and McKesson Corporation represented approximately 13%, 18% and 19%, respectively, of net revenues in fiscal 2007.

***Research and Development.*** Research and development expenses are charged to operations as incurred.

***Income Taxes.*** Income taxes have been provided for using an asset and liability approach in which deferred income taxes reflect the tax consequences on future years of events that the Company has already recognized in the financial statements or tax returns. Changes in enacted tax rates or laws will result in adjustments to the recorded tax assets or liabilities in the period that the new tax law is enacted.

***(Loss) Earnings per Common Share.*** Basic (loss) earnings per share excludes dilution and is computed by dividing net (loss) earnings available to common shareholders by the weighted average number of shares outstanding during the period. Diluted (loss) earnings per share is computed by dividing net (loss) earnings available to common shareholders by the weighted average number of shares outstanding during the period increased by the number of additional shares that would have been outstanding related to stock options, convertible instruments, warrants and other instruments indexed in the Company's stock if the impact is dilutive.

With respect to the Company's convertible preferred stock, the Company considered the effect on diluted earnings per share of the preferred stock conversion feature using the if-converted method. The preferred stock is convertible into between 125,234,172 shares and 152,785,775 shares of the Company's common stock, subject to anti-dilution adjustments, depending on the average stock price of its common stock over the 20 trading-day period ending on the third trading day prior to conversion. For the calendar year ended December 31, 2008 and the nine months ended December 31, 2007, the preferred stock conversion would have been anti-dilutive and, as such, was not assumed in the computation of diluted loss per share.

**Table of Contents**

Basic and diluted (loss) earnings per common share is calculated as follows:

	<b>Calendar Year Ended December 31, 2008</b>	<b>Nine Months Ended December 31, 2007</b>	<b>Fiscal Year Ended March 31, 2007</b>
<i>(in thousands, except per share amounts)</i>			
<b>Basic (loss) earnings available to common shareholders (numerator):</b>			
Net (loss) earnings before preferred dividends	\$ (181,215)	\$ (1,138,025)	\$ 217,284
Less: Preferred stock dividends	139,035	15,999	
Net (loss) earnings available to common shareholders	\$ (320,250)	\$ (1,154,024)	\$ 217,284
<b>Shares (denominator):</b>			
Weighted average shares outstanding	304,360	257,150	215,096
Basic (loss) earnings per common share	\$ (1.05)	\$ (4.49)	\$ 1.01
<b>Dilutive (loss) earnings available to common shareholders (numerator):</b>			
Net (loss) earnings available to common shareholders	\$ (320,250)	\$ (1,154,024)	\$ 217,284
Add: Preferred stock dividend			
Income available to common shareholders and assumed conversions	\$ (320,250)	\$ (1,154,024)	\$ 217,284
<b>Shares (denominator):</b>			
Stock-based awards			4,024
Preferred stock conversion			
Total dilutive shares outstanding assuming conversions	304,360	257,150	219,120
Diluted (loss) earnings per common share	\$ (1.05)	\$ (4.49)	\$ 0.99

Additional stock options or restricted stock awards representing 20.7 million, 12.5 million and 1.6 million shares were outstanding for the calendar year ended December 31, 2008, the nine months ended December 31, 2007, and fiscal year ended March 31, 2007, respectively, but were not included in the computation of diluted (loss) earnings per share because the effect would be anti-dilutive.

During the calendar year ended December 31, 2008, the Company paid dividends of \$137.5 million on the preferred stock. On January 29, 2009, the Company announced that a quarterly dividend of \$16.25 per share was declared

(based on the annual dividend rate of 6.5% and a liquidation preference of \$1,000 per share) payable on February 17, 2009, to the holders of preferred stock of record as of February 1, 2009.

**Stock Options.** The Company adopted SFAS No. 123 (revised 2004), *Share-Based Payment* ( SFAS No. 123R ), effective April 1, 2006. SFAS No. 123R requires the recognition of the fair value of stock-based compensation in net earnings. Prior to April 1, 2006, the Company accounted for its stock options using the intrinsic value method of accounting provided under Accounting Principles Board Opinion ( APB ) No. 25, *Accounting for Stock Issued to Employees*, ( APB No. 25 ), and related Interpretations, as permitted by SFAS No. 123, *Accounting for Share Based Compensation* ( SFAS No. 123 ).

**Table of Contents**

Mylan adopted the provisions of SFAS No. 123R, using the modified prospective transition method. Under this method, compensation expense recognized in the calendar year ended December 31, 2008, the nine-month period ended December 31, 2007, and the fiscal year ended March 31, 2007 includes: (a) compensation cost for all share-based payments granted prior to April 1, 2006, but for which the requisite service period had not been completed as of April 1, 2006 based on the grant date fair value, estimated in accordance with the original provisions of SFAS No. 123, and (b) compensation cost for all share-based payments granted subsequent to April 1, 2006, based on the grant date fair value estimated in accordance with the provisions of SFAS No. 123R.

**Foreign Currencies.** The Consolidated Financial Statements are presented in the reporting currency of Mylan, U.S. Dollars ( USD ). Statements of Operations and Cash Flows of all of the Company's subsidiaries that have functional currencies other than USD are translated at a weighted average exchange rate for the period, whereas assets and liabilities are translated at the end of the period exchange rates. Translation differences are recorded directly in shareholders' equity as cumulative translation adjustments. Gains or losses on transactions denominated in a currency other than the subsidiaries' functional currency, which arise as a result of changes in foreign currency exchange rates, are recorded in the Consolidated Statements of Operations.

**Derivatives.** From time to time the Company may enter into derivative instruments (mainly foreign currency exchange forward contracts, purchased currency options, interest rate swaps and purchased equity call options) designed to hedge the cash flows resulting from existing assets and liabilities and transactions expected to be entered into over the next twelve months, in currencies other than the functional currency, to hedge the variability in interest expense on floating rate debt or to hedge cash or share payments required on conversion of issued convertible notes. When such instruments qualify for hedge accounting under SFAS No. 133, *Accounting for Derivative Instruments and Hedging Activities* ( SFAS No. 133 ), they are recognized on the balance sheet with the change in the fair value recorded as a component of other comprehensive income until the underlying hedged item is recognized in the Consolidated Statements of Operations. When such derivatives do not qualify for hedge accounting under SFAS No. 133, they are recognized on the balance sheet at their fair value, with changes in the fair value recorded in the Consolidated Statements of Operations and included in other income, net.

**Financial Instruments.** The Company's financial instruments consist primarily of short-term and long-term debt, interest rate swaps, forward contracts, and option contracts. The Company's financial instruments also include cash and cash equivalents as well as accounts and other receivables and accounts payable, the fair values of which approximate their carrying values. As a policy, the Company does not engage in speculative or leveraged transactions, nor does the Company hold or issue financial instruments for trading purposes.

The Company uses derivative financial instruments for the purpose of hedging foreign currency and interest rate exposures, which exist as part of ongoing business operations or to hedge cash or share payments required on conversion of issued convertible notes. The Company carries derivative instruments on the balance sheet at fair value, determined by reference to market data such as forward rates for currencies, implied volatilities and interest rate swap yield curves. The accounting for changes in the fair value of a derivative instrument depends on whether it has been designated and qualifies as part of a hedging relationship and, if so, the reason for holding it.

**Use of Estimates in the Preparation of Financial Statements.** The preparation of financial statements, in conformity with accounting principles generally accepted in the United States of America ( GAAP ), requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Because of the uncertainty inherent in such estimates, actual results could differ from those estimates.

**Recent Accounting Pronouncements.** In June 2008, the Financial Accounting Standards Board ( FASB ) issued FASB Staff Position ( FSP ) No. EITF 03-6-1, *Determining Whether Instruments Granted in Share-Based Payment*

*Transactions Are Participating Securities* ( FSP No. EITF 03-6-1 ). FSP No. EITF 03-6-1 states that unvested share-based payment awards that contain nonforfeitable rights to dividends or dividend equivalents (whether paid or unpaid) are participating securities and shall be included in the computation of earnings per share pursuant to the two-class method. FSP No. EITF 03-6-1 is effective for fiscal years beginning after December 15, 2008. The adoption of FSP No. EITF 03-6-01 will not have a material impact on the Company's Consolidated Financial Statements.

**Table of Contents**

In May 2008, the FASB issued FSP No. APB 14-1, *Accounting for Convertible Debt Instruments That May Be Settled in Cash Upon Conversion (Including Partial Cash Settlement)* ( FSP No. APB 14-1 ). Under the new rules for convertible debt instruments (including our Senior Convertible Notes) that may be settled entirely or partially in cash upon conversion, an entity should 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 for the debentures is that the equity component would be included in the paid-in-capital section of stockholders' equity on our consolidated balance sheet and the value of the equity component would be treated as original issue discount for purposes of accounting for the debt component of the Senior Convertible Notes. FSP No. APB 14-1 will be effective for fiscal years beginning after December 15, 2008, and for interim periods within those fiscal years, with retrospective application required. Higher interest expense will result through the accretion of the discounted carrying value of the Senior Convertible Notes to their face amount over the term of the Senior Convertible Notes. Prior period interest expense will also be higher than previously reported interest expense due to retrospective application. Early adoption is not permitted. The Company evaluated the impact of adopting FSP No. APB 14-1 on its Consolidated Financial Statements and determined that the retrospective application will increase the net loss available to common shareholders by approximately \$10.0 million for the nine months ended December 31, 2007, and \$15.0 million for calendar year ended December 31, 2008. In addition, at December 31, 2008, additional paid-in capital will increase by \$85.0 million and long-term debt, retained earnings and tax assets will decrease by \$87.0 million, \$26.0 million and \$28.0 million, respectively.

In April 2008, the FASB issued FSP No. FAS 142-3, *Determination of the Useful Life of Intangible Assets* ( FSP No. FAS 142-3 ). FSP No. FAS 142-3 amends the factors that should be considered in developing renewal or extension assumptions used to determine the useful life of a recognized intangible asset under SFAS No. 142, *Goodwill and Other Intangible Assets* ( SFAS No. 142 ) in order to improve the consistency between the useful life of a recognized intangible asset under SFAS No. 142 and the period of expected cash flows used to measure the fair value of the asset under SFAS No. 141(R), *Business Combinations* ( SFAS No. 141(R) ), and other GAAP. FSP No. FAS 142-3 is effective for fiscal years beginning after December 15, 2008. The adoption of FSP No. FAS 142-3 will not have a material impact on the Company's Consolidated Financial Statements.

In March 2008, the FASB issued SFAS No. 161, *Disclosures about Derivative Instruments and Hedging Activities – an amendment of FASB Statement No. 133* ( SFAS No. 161 ). SFAS No. 161 requires enhanced disclosures about an entity's derivative and hedging activities, including (i) how and why an entity uses derivative instruments, (ii) how derivative instruments and related hedged items are accounted for under SFAS No. 133 and (iii) how derivative instruments and related hedged items affect an entity's financial position, financial performance, and cash flows. This standard is effective for fiscal years beginning after November 15, 2008. Management is currently assessing the impact of the disclosures on the Company's Consolidated Financial Statements.

In March 2008, the Emerging Issues Task Force ( EITF ) issued EITF No. 07-5, *Determining Whether an Instrument (or Embedded Feature) is Indexed to an Entity's Own Stock* ( EITF No. 07-5 ). EITF No. 07-5 states that if an instrument (or an embedded feature) has the characteristics of a derivative instrument under paragraphs 6-9 of SFAS No. 133, and is indexed to an entity's own stock, it is necessary to evaluate whether it is classified in shareholders' equity (or would be classified in shareholders' equity if it were a freestanding instrument). EITF No. 07-5 is effective for fiscal years beginning after December 15, 2008. The adoption of EITF No. 07-5 will not have a material impact on the Company's Consolidated Financial Statements.

On January 1, 2008, the Company adopted Statement 133 Implementation Issue No. E23, *Hedging – General: Issues Involving the Application of the Shortcut Method under Paragraph 58* ( Issue No. E23 ). Issue No. E23 provides guidance on certain practice issues related to the application of the shortcut method by amending paragraph 68 of SFAS No. 133 with respect to the conditions that must be met in order to apply the shortcut method for assessing hedge effectiveness of interest rate swaps. In addition to applying the provisions of Issue No. E23 on hedging arrangements designated on or after January 1, 2008, an assessment was required to be made on January 1, 2008 to

determine whether preexisting hedging arrangements met the provisions of Issue No. E23 as of their original inception. Management performed such an assessment and determined that the adoption of Issue No. E23 did not have a material impact on preexisting hedging arrangements.

**Table of Contents**

On January 1, 2008, the Company adopted SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities including an amendment of FASB Statement No. 115* ( SFAS No. 159 ). SFAS No. 159 permits entities to choose to measure many financial instruments and certain other assets and liabilities at fair value on an instrument-by-instrument basis (the fair value option) with changes in fair value reported in earnings. The Company already records marketable securities at fair value in accordance with SFAS No. 115, *Accounting for Certain Investments in Debt and Equity Securities* ( SFAS No. 115 ), and derivative contracts and hedging activities at fair value in accordance with SFAS No. 133. The adoption of SFAS No. 159 did not have a material impact on the Company's Consolidated Financial Statements as management did not elect the fair value option for any other financial instruments or certain other assets and liabilities.

In December 2007, the FASB issued SFAS No. 141(R). SFAS No. 141(R) replaces SFAS No. 141, *Business Combinations*, ( SFAS No. 141 ) and retains the fundamental requirements in SFAS No. 141, including that the purchase method be used for all business combinations and for an acquirer to be identified for each business combination. This standard defines the acquirer as the entity that obtains control of one or more businesses in the business combination and establishes the acquisition date as the date that the acquirer achieves control instead of the date that the consideration is transferred. SFAS No. 141(R) requires an acquirer in a business combination, including business combinations achieved in stages (step acquisition), to recognize the assets acquired, liabilities assumed, and any noncontrolling interest in the acquiree at the acquisition date, measured at their fair values at that date, with limited exceptions. It also requires the recognition of assets acquired and liabilities assumed arising from certain contractual contingencies as of the acquisition date, measured at their acquisition-date fair values. SFAS No. 141(R) is effective for any business combination with an acquisition date on or after January 1, 2009. The Company is currently evaluating the potential impact of SFAS No. 141(R) on the Consolidated Financial Statements.

In December 2007, the FASB issued SFAS No. 160, *Noncontrolling Interests in Consolidated Financial Statements an amendment of ARB No. 51* ( SFAS No. 160 ). SFAS No. 160 amends Accounting Research Bulletin No. 51, *Consolidated Financial Statements*, 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. SFAS No. 160 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. SFAS No. 160 is effective for fiscal years beginning after December 15, 2008. Although certain captions and disclosures will be revised, the adoption of SFAS No. 160 will not have a material impact on the Company's Consolidated Financial Statements.

In March 2007, the EITF issued EITF No. 06-10, *Accounting for Collateral Assignment Split-Dollar Life Insurance Arrangements* ( EITF No. 06-10 ). Under the provisions of EITF No. 06-10, an employer is required to recognize a liability for the postretirement benefit related to a collateral assignment split-dollar life insurance arrangement with the employee. The provisions of EITF No. 06-10 also require an employer to recognize and measure the asset in a collateral assignment split-dollar life insurance arrangement based on the nature and substance of the arrangement. The Company adopted the provisions of EITF No. 06-10 as of January 1, 2008. As a result of the adoption, the Company recognized a liability of \$8.3 million, representing the present value of the future premium payments to be made under the existing policies. In accordance with the transition provisions of EITF No. 06-10, this amount was recorded as a direct decrease to retained earnings.

In March 2007, the EITF issued EITF No. 06-04, *Accounting for Deferred Compensation and Postretirement Benefit Aspects of Endorsed Split-Dollar Life Insurance Arrangements* ( EITF No. 06-4 ), which concludes that an employer



should recognize a liability for post-employment benefits promised an employee based on the substantive arrangement between the employer and the employee. The Company adopted the provisions of EITF No. 06-04 as of January 1, 2008. The adoption of EITF No. 06-04 did not have a material impact on the Company's Consolidated Financial Statements.

**Table of Contents****Note 3. Acquisitions***Acquisition of the Former Merck Generics Business*

On May 12, 2007, Mylan and Merck KGaA announced the signing of a definitive agreement under which Mylan agreed to purchase Merck's generic pharmaceutical business in an all-cash transaction. On October 2, 2007, Mylan completed its acquisition of the former Merck Generics business.

In accordance with SFAS No. 141, the Company used the purchase method of accounting to account for this transaction. Under the purchase method of accounting, the assets acquired and liabilities assumed in the transaction were recorded at the date of acquisition at the estimate of their respective fair values.

The purchase price plus acquisition costs exceeded the estimate of fair values of acquired assets and assumed liabilities resulting in the recognition of goodwill in the preliminary amount of \$3.17 billion. This was a cash-free/debt-free transaction as defined in the Share Purchase Agreement (SPA). The total purchase price, including acquisition costs of \$38.7 million, was approximately \$7.0 billion. The operating results of the former Merck Generics business from October 2, 2007 are included in the Consolidated Financial Statements. The allocation of assets acquired and liabilities assumed for the former Merck Generics business as of the acquisition date is as follows:

*(in thousands)*

Current assets (excluding inventories)	\$ 765,495
Inventories	645,449
Property, plant and equipment, net <sup>(4)</sup>	344,454
Identified intangible assets	2,654,163
Other non-current assets <sup>(2)</sup>	140,015
In-process research and development <sup>(1)</sup>	1,269,036
Goodwill	3,166,005
Total assets acquired	8,984,617
Current liabilities <sup>(3)</sup>	(820,444)
Deferred tax liabilities	(1,020,040)
Other non-current liabilities	(142,203)
Net assets acquired	\$ 7,001,930

(1) The amount allocated to acquired in-process research and development represents an estimate of 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 fair value of the acquired in-process technology and research projects was based on the excess earnings method on a project-by-project basis. This amount was written-off upon acquisition as acquired in-process research and development expense.

(2) Included in non-current assets is \$137.1 million of receivables for the agreement of Merck KGaA under the terms of the SPA to indemnify Mylan for certain acquired significant litigation (see Note 19).

(3)

Included in current liabilities are \$74.3 million of restructuring reserves that impacted goodwill. These estimated exit costs are associated with involuntary termination benefits for the former Merck Generics business employees and costs to exit certain activities of the former Merck Generics business and were recorded as a liability in conjunction with recording the initial purchase price.

- (4) Included in property, plant and equipment are \$36.4 million of asset writedowns that have impacted goodwill. These writedowns relate to adjusting equipment and buildings down to their expected residual value upon their sale or closure.

At December 31, 2007, as a result of the Company's preliminary allocation of goodwill, approximately \$2.4 billion and \$711.2 million were allocated to its Generics Segment and Specialty Segment.

**Table of Contents**

As of December 31, 2008, the Company has finalized the purchase price allocation. Finalization of the purchase price allocation consisted of net adjustments to deferred tax liabilities, adjustments to certain asset fair values, and additional restructuring liabilities. During the calendar year ended December 31, 2008, a net decrease of approximately \$53.1 million was recorded to goodwill related to the finalization of the purchase price allocation (see Note 10).

The Company has finalized its plans to exit certain activities of the former Merck Generics business as of December 31, 2008. As a result, the Company has a \$67.0 million reserve at December 31, 2008 related to involuntary termination benefits and certain other exit costs accounted for in accordance with EITF No. 95-3, *Recognition of Liabilities in Conjunction with a Purchased Business Combination* ( EITF No. 95-3 ) (see Note 6).

In conjunction with the acquisition of the former Merck Generics business, the Company assumed certain loss contingencies. As disclosed in Note 19 Contingencies, Merck KGaA has indemnified Mylan under the provisions of the SPA for certain of these contingencies.

Also in conjunction with the acquisition, 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 contract was contingent upon the closing of the acquisition, and included a premium of \$121.9 million, which was paid upon such closing on October 2, 2007. The value of the foreign currency option contract fluctuated depending on the value of the U.S. dollar compared to the Euro. The Company accounted for this instrument under the provisions of SFAS No. 133. This instrument did not qualify for hedge accounting treatment under SFAS No. 133 and therefore was required to be adjusted to fair value with the change in the fair value of the instrument recorded in current earnings. The Company recorded a gain of \$85.0 million (net of the premium), during the nine-month period ended December 31, 2007, related to the deal-contingent foreign currency option contract. This amount is included within other income, net in the Consolidated Statements of Operations. In conjunction with the closing on October 2, 2007 of the acquisition of the former Merck Generics business, this foreign currency option contract was settled (net of the premium).

*Acquisition of Matrix Laboratories Limited*

On August 28, 2006, Mylan Inc. entered into a Share Purchase Agreement (the *Share Purchase Agreement* ) to acquire, through MP Laboratories (Mauritius) Ltd, its wholly-owned indirect subsidiary, a controlling interest in Matrix, a publicly traded company in India. Matrix is engaged in the manufacture of APIs and solid oral dosage forms and is headquartered in Hyderabad, India.

Pursuant to the Share Purchase Agreement, Mylan agreed to pay a cash purchase price of 306 Rupees per share for approximately 51.5% of the outstanding share capital of Matrix held by certain selling shareholders (the *Selling Shareholders* ).

In accordance with applicable Indian law, MP Laboratories (Mauritius) Ltd, along with the Company, commenced an open offer to acquire up to an additional 20% of the outstanding shares of Matrix (the *Public Offer* ) from Matrix's shareholders (other than the Selling Shareholders) on November 22, 2006, which Public Offer expired on December 11, 2006. The price in the Public Offer was 306 Rupees per share, in accordance with applicable Indian regulations.

On December 21, 2006, the Public Offer was completed and a total of 54,585,189 shares were validly tendered, of which Mylan accepted 30,836,662 shares. Payment in the amount of \$210.6 million for the shares properly tendered and accepted was dispatched to the shareholders. On January 8, 2007, Mylan completed its acquisition of approximately 51.5% of Matrix's outstanding shares from the Selling Shareholders for approximately \$545.6 million,

thereby increasing its ownership to approximately 71.5% of the voting share capital of Matrix. Including the Matrix shareholdings maintained by Prasad Nimmagadda (one of the Selling Shareholders), which are subject to a voting arrangement with Mylan, Mylan controls in excess of 75% of the voting share capital of Matrix.

Following the closing of this transaction, certain of the Selling Shareholders used approximately \$168.0 million of their proceeds to acquire Mylan Inc. common stock from the Company in a private sale at a price of \$20.85 per share. In connection with these transactions a total of 8,058,139 shares were issued to the Selling

**Table of Contents**

Shareholders. For purchase accounting purposes, the Company valued these shares at \$20.32 per share, which represents Mylan's average stock price for the period two business days before and two business days after the August 28, 2006 announcement of the acquisition.

As a result of Mylan's aggregate ownership in Matrix, Mylan accounted for this transaction as a purchase under SFAS No. 141 and has consolidated the results of operations of Matrix since January 8, 2007. The purchase price has been allocated to the fair value of the tangible and intangible assets and liabilities with the excess being recorded as goodwill as of the effective date of the acquisition. As the acquisition was structured as a purchase of equity, the amortization of the portion of the purchase price assigned to assets in excess of Matrix's historic tax basis will not be deductible for income tax purposes.

The total purchase price of \$776.2 million, including acquisition costs of \$24.3 million, less cash acquired of \$10.9 million, was \$765.2 million. The allocation of assets acquired and liabilities assumed for Matrix is as follows:

*(in thousands)*

Current assets (excluding cash and inventories)	\$ 129,621
Inventories	123,000
Property, plant and equipment, net	152,580
Identified intangible assets	270,440
Other non-current assets	65,878
In-process research and development <sup>(1)</sup>	147,000
Goodwill	505,801
Total assets acquired	1,394,320
Current liabilities	(374,458)
Deferred tax liabilities	(106,470)
Other non-current liabilities	(104,045)
Total liabilities assumed	(584,973)
Total minority interest	(44,117)
Net assets acquired	\$ 765,230

<sup>(1)</sup> The amount allocated to acquired in-process research and development represents an estimate of 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 fair value of the acquired in-process technology and research projects was based on the excess earnings method on a project-by-project basis. This amount was written-off upon acquisition as acquired in-process research and development expense.

In conjunction with the Matrix transaction, the Company entered into a 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. The Company accounted for this instrument under the provisions of SFAS No. 133. This instrument did not qualify for hedge accounting treatment under SFAS No. 133 and therefore was required to be adjusted to fair value with the change in the fair value of the instrument recorded in current earnings. The Company recorded a gain of \$16.2 million for the fiscal year ended March 31, 2007 related to this deal-contingent

forward contract. This amount is included within other income, net in the Consolidated Statements of Operations.

*Pro forma financial results*

The operating results of the former Merck Generics business have been included in Mylan's Consolidated Financial Statements since October 2, 2007. The operating results of Matrix have been included in Mylan's Consolidated Financial Statements since January 8, 2007. Pro forma results of operations for the nine months ended December 31, 2007 included below assumes that the former Merck Generics business acquisition occurred on April 1, 2007. Matrix's actual results of operations are included in the calendar year ended December 31, 2008 and

**Table of Contents**

the nine months ended December 31, 2007. Pro forma results of operations for the fiscal year ended March 31, 2007 included below assume both acquisitions occurred on April 1, 2006. This summary of the unaudited pro forma results of operations is not necessarily indicative of what Mylan's results of operations would have been had the former Merck Generics business and Matrix been acquired at the beginning of the periods indicated, nor does it purport to represent results of operations for any future periods.

The unaudited pro forma financial information for each of periods below includes the following material, non-recurring charges directly attributable to the accounting for the acquisitions: In the nine-month period ended December 31, 2007, amortization of the step-up of inventory of \$109.4 million and an acquired in-process research and development charge of \$1.27 billion for the former Merck Generics business. For the fiscal year ended March 31, 2007, \$141.7 million related to the amortization of the step-up of inventory and an acquired in-process research and development charge of \$147.0 million for Matrix and \$1.27 billion for the former Merck Generics business. In addition, the pro forma financial information for each period presented includes the effects of the preferred and common stock offerings closed in November 2007, the proceeds of which were used to repay the Interim Term Loans (see Notes 12 and 14).

	<b>Nine Months Ended December 31, 2007</b>	<b>Fiscal Year Ended March 31, 2007</b>
<i>(in thousands, except per share data)</i>		
Total revenues	\$ 3,428,231	\$ 4,197,786
Net loss before preferred dividend	\$ (1,290,242)	\$ (1,311,466)
Preferred dividend	(104,276)	(121,656)
Net loss available to common shareholders	\$ (1,394,518)	\$ (1,433,122)
Loss per common share		
Basic	\$ (4.91)	\$ (5.35)
Diluted	\$ (4.91)	\$ (5.35)
Weighted average shares		
Basic	283,900	267,984
Diluted	283,900	267,984

In July 2008, Mylan purchased from Watson Pharmaceutical Inc. a 50% interest in the outstanding shares of Somerset Pharmaceuticals, Inc. Mylan had previously owned the other 50% of Somerset and had accounted for the investment using the equity method. This acquisition was not material to the Company's statements of financial position, results of operations, or cash flows.

**Note 4. Impairment of Long-lived Assets Including Goodwill**

On February 27, 2008, the Company announced that it was reviewing strategic alternatives for its 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<sup>®</sup> 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 its ongoing review of strategic alternatives, the Company 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 in accordance with SFAS No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets* ( SFAS No. 144 ). The Company 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.

**Table of Contents**

Upon the closing of the former Merck Generics business acquisition, Dey was defined as the Specialty Segment under the provisions of SFAS No. 131. Dey is also considered a reporting unit under the provisions of SFAS No. 142. Upon closing of the transaction, the Company allocated \$711.2 million of goodwill to Dey.

The Company tests 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 the Company 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, the Company was 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 SFAS No. 142 impairment analysis consisted of a comparison of the fair value of the reporting unit with its carrying amount, including the goodwill. The Company performed extensive valuation analyses, utilizing both income and market-based approaches, in its 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, the Company discounted the expected future cash flows of the reporting unit, using 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 its model, the Company used a terminal value approach. Under this approach, the Company used estimated operating income before interest, taxes, depreciation and amortization in the final year of its 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. The Company incorporated the present value of the resulting terminal value into its estimate of fair value.

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

Based on the SFAS No. 142 step one analysis that was performed for Dey, the Company determined that the carrying amount of the net assets of the reporting unit was in excess of its estimated fair value. As such, the Company was 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, the Company concluded that \$385.0 million of the goodwill recorded at Dey was impaired. As a result, the Company recorded a non-cash goodwill impairment charge of \$385.0 million during the three months ended March 31, 2008, which represented its best estimate as of March 31, 2008. The allocation discussed above was performed only for purposes of assessing goodwill for impairment; accordingly, Mylan has not adjusted the net book value of the assets and liabilities on the Company's Consolidated Balance Sheet, other than goodwill, as a result of this process.

The determination of the fair value of the reporting unit required the Company 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 the Company 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 (see Note 10).

In September 2008, following the completion of the comprehensive review of strategic alternatives for Dey, the Company announced its decision to retain the Dey business. This decision included a plan to realign the

**Table of Contents**

business, including positioning the Company to divest Dey's current facilities over the next two years (see Note 6). As a result, the Company expects to incur severance and other exit costs. In addition, the comprehensive review resulted in the impairment of certain non-core, insignificant, third-party products.

**Note 5. Revenue Recognition**

In January 2006, the Company 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.

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 one-time 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. The Company believes that it no longer has significant continuing involvement and that the earnings process has been completed. As such, the remaining deferred revenue of \$455.0 million was recognized and included in other revenues in the Company's Consolidated Statements of Operations.

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

**Note 6. Restructuring**

The Company's Consolidated Balance Sheet as of December 31, 2008, includes a \$67.0 million restructuring reserve, which relates to certain estimated exit costs associated with the acquisition of the former Merck Generics business. The plans related to these exit activities have now been finalized. Payments of approximately \$9.4 million were made during the calendar year ended December 31, 2008, of which \$6.1 million were severance costs and the remaining \$3.3 million were other exit costs.

The Company announced its intent to restructure certain activities and incur certain related exit costs, including related to the realignment of the Dey business. In accordance with the provisions of SFAS No. 146, *Accounting for Costs Associated with Exit or Disposal Activities* ( SFAS No. 146 ), the Company has recorded a reserve for such activities of which approximately \$8.0 million remains at December 31, 2008 and made payments of approximately \$0.7 million. In addition, the Company recorded approximately \$3.7 million for the acceleration of depreciation expense, during the calendar year ended December 31, 2008. As finalization of the plans are still in progress, the Company has not yet estimated the total amount expected to be incurred in connection with such activities. However,

Mylan expects the majority of such costs will relate to one-time termination benefits and certain asset write-downs and could be significant.

**Table of Contents****Note 7. Comparative Nine-Month Financial Information**

Effective as of October 2, 2007, the Board of Directors of Mylan approved a change to its fiscal year end from March 31st to December 31st. Consolidated Statements of Operations for the nine months ended December 31, 2007 and 2006 are summarized below. All data for the nine months ended December 31, 2006 are derived from the Company's unaudited Condensed Consolidated Financial Statements.

**MYLAN INC. AND SUBSIDIARIES****Consolidated Statements of Operations**

<b>Nine Months Ended December 31,</b>	<b>2007</b>	<b>2006</b>
<i>(in thousands, except per share amounts)</i>		<b>(Unaudited)</b>
Revenues		
Net revenues	\$ 2,162,943	\$ 1,103,247
Other revenues	15,818	21,310
Total revenues	2,178,761	1,124,557
Cost of sales	1,304,313	515,736
Gross profit	874,448	608,821
Operating expenses:		
Research and development	146,063	66,844
Acquired in-process research and development	1,269,036	
Selling, general and administrative	449,598	152,784
Litigation settlements, net	(1,984)	(46,154)
Total operating expenses	1,862,713	173,474
(Loss) earnings from operations	(988,265)	435,347
Interest expense	179,410	31,292
Other income, net	86,611	39,785
(Loss) earnings before income taxes and minority interest	(1,081,064)	443,840
Provision for income taxes	60,073	155,267
(Loss) earnings before minority interest	(1,141,137)	288,573
Minority interest income	3,112	
Net (loss) earnings before preferred dividends	(1,138,025)	288,573
Preferred dividend	15,999	
Net (loss) earnings available to common shareholders	(1,154,024)	288,573
(Loss) earnings per common share:		

Edgar Filing: MYLAN INC. - Form 10-K

Basic	\$	(4.49)	\$	1.37
Diluted	\$	(4.49)	\$	1.34
Weighted average common shares outstanding:				
Basic		257,150		211,075
Diluted		257,150		215,275

**Table of Contents****Note 8. Balance Sheet Components**

Selected balance sheet components consisted of the following:

<i>(in thousands)</i>	<b>December 31, 2008</b>	<b>December 31, 2007</b>
Inventories:		
Raw materials	\$ 273,232	\$ 255,744
Work in process	157,473	160,918
Finished goods	635,285	647,178
	\$ 1,065,990	\$ 1,063,840
Property, plant and equipment:		
Land and improvements	\$ 56,945	\$ 62,824
Buildings and improvements	577,182	583,097
Machinery and equipment	1,012,748	980,340
Construction in progress	110,721	125,682
	1,757,596	1,751,943
Less accumulated depreciation	693,600	649,011
	\$ 1,063,996	\$ 1,102,932
Other current liabilities:		
Payroll and employee benefit plan accruals	\$ 181,316	\$ 136,232
Accrued rebates	236,312	301,829
Fair value of financial instruments	91,797	
Legal and professional accruals	71,813	58,883
Other	127,400	148,186
	\$ 708,638	\$ 645,130

**Note 9. Available-for-Sale Fixed Income Securities**

The amortized cost and estimated fair value of available-for-sale fixed income securities were as follows:

<i>(in thousands)</i>	<b>Amortized Cost</b>	<b>Gross Unrealized Gains</b>	<b>Gross Unrealized Losses</b>	<b>Fair Value</b>
<b>December 31, 2008</b>				
Debt securities	\$ 42,146	\$ 1,772	\$ (2,260)	\$ 41,658



Edgar Filing: MYLAN INC. - Form 10-K

Equity securities			602		602
	\$ 42,146	\$ 2,374		\$ (2,260)	\$ 42,260
<b><u>December 31, 2007</u></b>					
Debt securities	\$ 88,806	\$ 1,748		\$ (315)	\$ 90,239
Equity securities			1,122		1,122
	\$ 88,806	\$ 2,870		\$ (315)	\$ 91,361

**Table of Contents**

Maturities of debt securities at fair value as of December 31, 2008, were as follows:

*(in thousands)*

Mature within one year	\$ 2,819
Mature in one to five years	14,115
Mature in five years and later	24,724
	\$ 41,658

Gross gains of \$0.1 million, \$1.8 million and \$0.8 million and gross losses of \$0.2 million, \$1.5 million and \$1.8 million were realized during the calendar year ended December 31, 2008, the nine months ended December 31, 2007 and fiscal year 2007, respectively.

The Company also had approximately \$9.1 million and \$40.6 million of auction rate securities ( ARS ) at December 31, 2008 and December 31, 2007. During the nine months ended December 31, 2007, no auctions failed. During the calendar year ended December 31, 2008, the securities were subject to a failed auction in May 2008. These ARS continue to pay interest according to their terms. The securities were issued by a state educational loan authority and are backed by student loans. The state educational loan authority has requested and received required consent from bondholders to amend the existing indentures governing the securities to add a call provision, which permits the securities to be called at par after August 1, 2008. The Company does not believe these securities are subject to any impairment as the Company has the intent and the ability to hold these securities until maturity or until called.

**Note 10. Goodwill and Other Intangible Assets**

A rollforward of goodwill from December 31, 2007 to December 31, 2008 and from March 31, 2007 to December 31, 2007 is as follows:

	<b>Total</b>
<i>(in thousands)</i>	
Goodwill balance at December 31, 2007	\$ 3,855,971
Impairment loss on goodwill	(385,000)
Foreign currency translation and other	(309,391)
Goodwill balance at December 31, 2008	\$ 3,161,580

	<b>Total</b>
<i>(in thousands)</i>	
Goodwill balance at March 31, 2007	\$ 612,742
Acquisition of Merck Generics	3,166,005
Foreign currency translation and other	77,224

Goodwill balance at December 31, 2007

\$ 3,855,971

Included in foreign currency translation and other for the calendar year ended December 31, 2008 is an approximate \$53.1 million net decrease to goodwill related to the finalization of the Merck Generics acquisition purchase price allocation. Finalization of the purchase price allocation consisted of net adjustments to deferred tax liabilities, adjustments to certain asset fair values, and additional restructuring liabilities.

At December 31, 2008, approximately \$2.39 billion, \$320.0 million and \$455.4 million were allocated to our Generics Segment, Specialty Segment and Matrix Segment, respectively.

**Table of Contents**

Intangible assets consist of the following components:

	<b>Weighted Average Life (Years)</b>	<b>Original Cost</b>	<b>Accumulated Amortization</b>	<b>Net Book Value</b>
<i>(dollars in thousands)</i>				
<b>December 31, 2008</b>				
Amortized intangible assets:				
Patents and technologies	20	\$ 118,926	\$ 71,631	\$ 47,295
Product rights and licenses	10	2,738,191	433,169	2,305,022
Other	8	129,563	28,719	100,844
		\$ 2,986,680	\$ 533,519	\$ 2,453,161
<b>December 31, 2007</b>				
Amortized intangible assets:				
Patents and technologies	20	\$ 118,926	\$ 65,578	\$ 53,348
Product rights and licenses	10	2,961,712	152,865	2,808,847
Other	8	129,031	12,520	116,511
		\$ 3,209,669	\$ 230,963	\$ 2,978,706

Other intangibles consist principally of customer lists and contracts. As a result of the acquisition of a controlling interest in Matrix the Company recorded intangible assets of \$270.4 million, primarily product rights and licenses, which have a weighted average useful life of eight years. As a result of the acquisition of the former Merck Generics business, the Company recorded intangible assets of \$2.65 billion, primarily product rights and licenses, which have a weighted average useful life of 10 years (see Note 3).

Amortization expense, which is classified within cost of sales on the Company's Consolidated Statements of Operations, for the calendar year ended December 31, 2008, the nine months ended December 31, 2007 and the fiscal year ended March 31, 2007 was \$368.2 million, \$100.7 million and \$22.4 million, respectively, and is expected to be \$298.5 million, \$291.6 million, \$283.1 million, \$267.7 million and \$244.8 million for the years ended December 31, 2009 through 2013, respectively.

Included within amortization expense for calendar year ended December 31, 2008, is approximately \$65.7 million of non-cash intangible impairment charges related primarily to certain non-core, insignificant, third-party manufactured products and assets.

**Note 11. Financial Instruments and Risk Management***Foreign Currency Exchange Risk*

A significant portion of the Company's revenues and earnings are exposed to changes in foreign currency exchange rates. The Company seeks to manage its 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 hedge the potential earnings effects from mostly intercompany foreign currency assets and liabilities that arise from operations and from intercompany loans.

The Company enters into financial instruments to hedge or offset, by the same currency, a portion of the currency risk and the timing of the hedged or offset item.

**Table of Contents**

As of December 31, 2008, the more significant financial instruments employed to manage foreign exchange risk are as follows:

812.4 million (\$1.13 billion) of borrowings under the Senior Credit Agreement that are designated as a hedge of our net investment in certain Euro-functional currency subsidiaries. The after-tax impact of revaluing these borrowings due to changes in spot exchange rates is included in the foreign currency translation adjustment component of other comprehensive (loss) earnings in the Consolidated Statements of Shareholders' Equity.

\$489.6 million net notional value of foreign exchange forward contracts maturing within one month that serve to offset changes in spot exchange rates of intercompany foreign currency denominated assets or liabilities. The Company recognizes the earnings impact of these contracts in other income, net in the Consolidated Statements of Operations during the terms of the contracts, along with the earnings impact of the items they generally offset.

As of December 31, 2007, the more significant financial instruments employed to manage foreign exchange risk are as follows:

875.4 million (\$1.23 billion) of borrowings under the Senior Credit Agreement that are designated as a hedge of our net investment in certain Euro-functional currency subsidiaries. The after-tax impact of revaluing these borrowings due to changes in spot exchange rates is included in the foreign currency translation adjustment component of other comprehensive (loss) earnings in the Consolidated Statements of Shareholders' Equity.

\$345.6 million net notional value of foreign exchange forward contracts maturing within one month that serve to offset changes in spot exchange rates of intercompany foreign currency denominated assets or liabilities. The Company recognizes the earnings impact of these contracts in other income, net in the Consolidated Statements of Operations during the terms of the contracts, along with the earnings impact of the items they generally offset.

All derivative contracts used to manage foreign currency exchange risk are measured at fair value and reported as assets or liabilities on the balance sheet. Any ineffectiveness in a hedging relationship is recognized immediately into earnings. There was no significant ineffectiveness during the calendar year ended December 31, 2008 or the nine months ended December 31, 2007.

*Interest Rate Risk*

The Company's interest-bearing investments and borrowings are subject to interest rate risk. The Company invests primarily on a variable-rate basis. The Company borrows on both a fixed and variable-rate basis. From time to time, depending on market conditions, the Company will fix interest rates either through entering into fixed-rate borrowings or through the use of derivative financial instruments.

In 2008, the Company executed the following interest rate derivatives in order to fix the interest rate on a portion of the Company's variable-rate U.S. Tranche B Term Loans under the Senior Credit Agreement. These swaps are designated as cash flow hedges of expected future borrowings under the Senior Credit Agreement.

\$500.0 million of notional interest rate swaps that fix a rate of 5.44% until March 2010

\$500.0 million of notional interest rate swaps that fix a rate of 6.03% until December 2010

During the nine months ended December 31, 2007, the Company executed \$1.0 billion of notional interest rate swaps in order to fix the interest rate on a portion of the Company's U.S. Tranche B Term Loans under the Senior Credit Agreement (see Note 12). These swaps are designated as cash flow hedges of the variability of interest expense related to our variable rate debt and fix a rate of 7.37% until December 2010.

The Company recognizes the earnings impact of the interest rate swaps in interest expense in the Company's Consolidated Statements of Operations upon the recognition of the interest related to the hedged items.

**Table of Contents**

All derivative contracts used to manage interest rate risk are measured at fair value and reported as assets or liabilities on the balance sheet. Changes in fair value are reported in earnings or deferred, depending on the nature and effectiveness of the offset. Any ineffectiveness in a hedging relationship is recognized immediately in earnings. There was no significant ineffectiveness during the calendar year ended December 31, 2008 or the nine months ended December 31, 2007.

In February 2009, the Company executed an additional 200.0 (\$277.8) million of notional interest rate swaps in order to fix the interest rate on a portion of our Euro Tranche B Term Loans. This swap fixes a rate of 5.38% on a portion of the Company's variable rate debt until March 2011 and are designated as a cash flow hedge of expected future borrowings under the Senior Credit Agreement.

*Equity Risk*

From time to time the Company may enter into derivative instruments to hedge cash or share-based payments required on conversion of issued convertible notes.

*Fair Value Measurement*

On January 1, 2008, the Company adopted SFAS No. 157, *Fair Value Measurements*, ( SFAS No. 157 ) for financial assets and liabilities and any other assets and liabilities carried at fair value. This pronouncement defines fair value, establishes a framework for measuring fair value and expands disclosures about fair value measurements. The Company's adoption of SFAS No. 157 did not have a material effect on the Company's Condensed Consolidated Financial Statements for financial assets and liabilities and any other assets and liabilities carried at fair value.

Effective September 30, 2008, the Company adopted FSP No. FAS 157-3, *Determining the Fair Value of a Financial Asset when the Market for that Asset is not Active*, ( FSP No. FAS 157-3 ). FAS No. FAS 157-3 clarifies the application of SFAS No. 157 in a market that is not active and provides an example to illustrate key considerations in determining the fair value of a financial asset when the market for that financial asset is not active. The Company's adoption of FSP No. FAS 157-3 did not have a material impact on the Company's Condensed Consolidated Financial Statements.

As defined in SFAS No. 157, fair value is based on the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. In order to increase consistency and comparability in fair value measurements, SFAS No. 157 establishes a fair value hierarchy that prioritizes observable and unobservable inputs used to measure fair value into three broad levels, which are described below:

*Level 1:* Quoted prices (unadjusted) in active markets that are accessible at the measurement date for assets or liabilities. The fair value hierarchy gives the highest priority to Level 1 inputs.

*Level 2:* Observable prices that are based on inputs not quoted on active markets, but corroborated by market data.

*Level 3:* Unobservable inputs are used when little or no market data is available. The fair value hierarchy gives the lowest priority to Level 3 inputs.

In determining fair value, the Company utilizes valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible as well as considers counterparty credit risk in its assessment of fair value.





**Table of Contents**

Financial assets and liabilities carried at fair value as of December 31, 2008 are classified in the table below in one of the three categories described above:

<b>Financial Assets</b> <i>(in thousands)</i>	<b>Level 1</b>	<b>Level 2</b>	<b>Level 3</b>	<b>Total</b>
Available-for-sale fixed income investments	\$	\$ 32,583	\$	\$ 32,583
Available-for-sale equity securities	602			602
Foreign exchange derivative assets		14,632		14,632
Purchased cash convertible note hedge		235,750		235,750
Auction rate securities <sup>(2)</sup>			9,075	9,075
<b>Total assets at fair value<sup>(1)</sup></b>	<b>\$ 602</b>	<b>\$ 282,965</b>	<b>\$ 9,075</b>	<b>\$ 292,642</b>

  

<b>Financial Liabilities</b> <i>(in thousands)</i>	<b>Level 1</b>	<b>Level 2</b>	<b>Level 3</b>	<b>Total</b>
Foreign exchange derivative liabilities	\$	\$ 19,402	\$	\$ 19,402
Interest rate swap derivative liabilities		72,395		72,395
Cash conversion feature of cash convertible notes		235,750		235,750
<b>Total liabilities at fair value<sup>(1)</sup></b>	<b>\$</b>	<b>\$ 327,547</b>	<b>\$</b>	<b>\$ 327,547</b>

(1) The Company chose not to elect the fair value option as prescribed by SFAS No. 159 for its financial assets and liabilities that had not been previously carried at fair value. Therefore, material financial assets and liabilities such as short-term and long-term debt obligations and trade accounts receivable and payable, are still reported at their carrying values.

(2) There have been no changes to the fair value of these securities during the quarter ended December 31, 2008.

Due to the lack of observable market quotes on the Company's ARS portfolio, the Company utilizes valuation models that rely exclusively on Level 3 inputs, including those that are based on expected cash flow streams and collateral values. The Company has approximately \$9.1 million in ARS, which were subject to a failed auction in May 2008. These ARS continue to pay interest according to their terms. The securities were issued by a state educational loan authority and are backed by student loans. The state educational loan authority has requested and received required consent from bondholders to amend the existing indentures governing the securities to add a call provision, which permits the securities to be called at par after August 1, 2008. The Company does not believe these securities are subject to any other than temporary impairment as the Company has the intent and the ability to hold these securities until maturity or until called.

For financial assets and liabilities that utilize Level 2 inputs, the Company utilizes both direct and indirect observable price quotes, including the LIBOR yield curve, foreign exchange forward prices, and bank price quotes. Below is a summary of valuation techniques for Level 1 and Level 2 financial assets and liabilities:

*Municipal bonds* valued at the quoted market price from broker or dealer quotations or transparent pricing sources at the reporting date.

*Other available-for-sale fixed income investments* valued at the quoted market price from broker or dealer quotations or transparent pricing sources at the reporting date.

*Equity Securities* valued using quoted stock prices from the London Exchange at the reporting date and translated to U.S. dollars at prevailing spot exchange rates.

*Interest rate swap derivative assets and liabilities* valued using the LIBOR yield curve at the reporting date. Counterparties to these contracts are highly rated financial institutions, none of which experienced any significant downgrades during the calendar year ended December 31, 2008, that would reduce the receivable amount owed, if any, to the Company.

**Table of Contents**

*Foreign exchange derivative assets and liabilities* valued using quoted forward foreign exchange prices at the reporting date. Counterparties to these contracts are highly rated financial institutions, none of which experienced any significant downgrades during the calendar year ended December 31, 2008, that would reduce the receivable amount owed, if any, to the Company.

*Cash Conversion Feature of Cash Convertible Notes and Purchased Convertible Note Hedge* valued using quoted prices for the Company's cash convertible notes, its implied volatility and the quoted yield on the Company's other long-term debt at the reporting date. Counterparties to the Purchased Convertible Note Hedge are highly rated financial institutions, none of which experienced any significant downgrades during the calendar year ended December 31, 2008, that would reduce the receivable amount owed, if any, to the Company.

Although the Company has not elected the fair value option for financial assets and liabilities existing at January 1, 2008 or transacted during the calendar year ended December 31, 2008, any future transacted financial asset or liability will be evaluated for the fair value election as prescribed by SFAS No. 159 and adjusted to fair value as determined under the provisions of SFAS No. 157.

**Note 12. Long-Term Debt**

A summary of long-term debt is as follows:

<i>(in thousands)</i>	<b>December 31, 2008</b>	<b>December 31, 2007</b>
U.S. Tranche A Term Loans <sup>(A)</sup>	\$ 265,625	\$ 312,500
Euro Tranche A Term Loans <sup>(A)</sup>	413,684	516,127
U.S. Tranche B Term Loans <sup>(A)</sup>	2,504,880	2,556,000
Euro Tranche B Term Loans <sup>(A)</sup>	714,583	773,273
Revolving Facility <sup>(A)</sup>		300,000
Senior Convertible Notes <sup>(B)</sup>	600,000	600,000
Cash Convertible Notes <sup>(C)</sup>	655,442	
Other	14,586	54,194
	\$ 5,168,800	\$ 5,112,094
Less: Current portion	3,381	405,378
Total long-term debt	\$ 5,165,419	\$ 4,706,716

<sup>(A)</sup> On October 2, 2007, the Company entered into a credit agreement (the "Senior Credit Agreement") among the Company, a wholly-owned European subsidiary (the "Euro Borrower"), certain lenders and JPMorgan Chase Bank, National Association, as Administrative Agent, pursuant to which the Company borrowed \$500.0 million in Tranche A Term Loans (the "U.S. Tranche A Term Loans") and \$2.0 billion in Tranche B Term Loans (the "U.S. Tranche B Term Loans"), and the Euro Borrower borrowed approximately 1.13 billion (\$1.6 billion) in Euro Term Loans (the "Euro Term Loans" and, together with the U.S. Tranche A Term Loans and the U.S. Tranche B Term Loans, the "Term Loans"). The proceeds of the Term Loans were used (1) to pay a portion of the consideration for

the acquisition of the former Merck Generics business, (2) to refinance the 2007 credit facility and the 2006 credit facility, (together the Existing Credit Agreements ), by and among the Company, the lenders party thereto and JPMorgan Chase Bank, National Association, as administrative agent, (3) to purchase the Senior Notes tendered pursuant to the cash tender offers therefore and (4) to pay a portion of the fees and expenses in respect of the foregoing transactions (collectively, the Transactions ). The termination of the Existing Credit Agreements was concurrent with, and contingent upon, the effectiveness of the Senior Credit Agreement. The Senior Credit Agreement also contains a \$750.0 million revolving facility (the Revolving Facility and, together with the Term Loans, the Senior Credit Facilities ) under which either the Company or the Euro Borrower may obtain extensions of credit, subject to the satisfaction of specified conditions. In conjunction with the closing of the former Merck Generics business acquisition the

**Table of Contents**

Company borrowed \$300.0 million under the Revolving Facility. The Revolving Facility includes a \$100.0 million subfacility for the issuance of letters of credit and a \$50.0 million subfacility for swingline borrowings. Borrowings under the Revolving Facility are available in U.S. dollars, Euro, Pounds Sterling, Yen or other currencies that may be agreed. The Euro Term Loans are guaranteed by the Company and the Senior Credit Facilities are guaranteed by substantially all of the Company's domestic subsidiaries (the Guarantors). The Senior Credit Facilities are also secured by a pledge of the capital stock of substantially all direct subsidiaries of the Company and the Guarantors (limited to 65% of outstanding voting stock of foreign holding companies and any foreign subsidiaries) and substantially all of the other tangible and intangible property and assets of the Company and the Guarantors. The Revolving Facility expires in October 2013.

The U.S. Tranche A Term Loans currently bear interest at LIBOR (determined in accordance with the Senior Credit Agreement) plus 3% per annum, if the Company chooses to make LIBOR borrowings, or at a base rate (determined in accordance with the Senior Credit Agreement) plus 2% per annum. The U.S. Tranche B Term Loans currently bear interest at LIBOR (determined in accordance with the Senior Credit Agreement) plus 3.25% per annum, if the Company chooses to make LIBOR borrowings, or at a base rate (determined in accordance with the Senior Credit Agreement) plus 2.25% per annum. The Euro Tranche A Term Loans currently bear interest at the Euro Interbank Offered Rate (EURIBO) determined in accordance with the Senior Credit Agreement) plus 3% per annum. The Euro Tranche B Term Loans currently bear interest at the EURIBO determined in accordance with the Senior Credit Agreement) plus 3.25% per annum. Borrowings under the Revolving Facility currently bear interest at LIBOR (or EURIBO, in the case of borrowings denominated in Euro) plus 2.50% per annum, if the Company chooses to make LIBOR (or EURIBO, in the case of borrowings denominated in Euro) borrowings, or at a base rate plus 1.50% per annum. The applicable margins over LIBOR, EURIBO or the base rate for the Revolving Facility and the U.S. Tranche A Term Loans can fluctuate based on a calculation of the Company's Consolidated Leverage Ratio as defined in the Senior Credit Agreement. The Company also pays a facility fee on the entire amount of the Revolving Facility. The facility fee is currently 0.50% per annum, but can decrease to 0.375% per annum based on the Company's Consolidated Leverage Ratio.

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.

The Senior Credit Agreement contains default provisions customary for facilities of this type, which are subject to customary grace periods and materiality thresholds, including, among other things, defaults related to payment failures, failure to comply with covenants, misrepresentations, defaults or the occurrence of a change of control under other material indebtedness, bankruptcy and related events, material judgments, certain events related to pension plans, specified changes in control of the Company and invalidity of guarantee and security agreements. If an event of default occurs under the Senior Credit Agreement, the lenders may, among other things, terminate their commitments, declare immediately payable all borrowings and foreclose on the collateral.

The U.S. Tranche A Term Loans and the Euro Tranche A Term Loans mature on October 2, 2013. The U.S. Tranche B Term Loans and the Euro Tranche B Term Loans mature on October 2, 2014. The U.S. Tranche B Term Loans and the Euro Term Loans amortize quarterly at the rate of 1.0% per annum beginning in 2008. The Senior Credit Agreement requires prepayments of the Term Loans with (1) up to 50% of Excess Cash Flow, as

defined within the Senior Credit Agreement, beginning in 2009, with reductions based on the Company's Consolidated Leverage Ratio, (2) the proceeds from certain asset sales and casualty events, unless the Company's Consolidated Leverage Ratio is equal to or less than 3.5 to 1.0, and (3) the proceeds from certain issuances of indebtedness not permitted by the Senior Credit Agreement. Amounts drawn on the Revolving

**Table of Contents**

Facility become due and payable on October 2, 2013. The Term Loans and amounts drawn on the Revolving Facility may be voluntarily prepaid without penalty or premium.

In addition, on October 2, 2007, the Company entered into a credit agreement (the Interim Credit Agreement ) among the Company, certain lenders and Merrill Lynch Capital Corporation, as Administrative Agent, pursuant to which the Company borrowed \$2.85 billion in term loans (the Interim Term Loans ). The proceeds of the Interim Term Loans were used to finance in part the acquisition of the former Merck Generics business. On November 19, 2007, the Interim Term Loans were paid using primarily the proceeds received from the preferred stock and common stock issuances of \$2.82 billion and the remaining \$28.1 million was paid using existing cash of the Company.

On December 20, 2007, the Euro Borrower, certain lenders and the Administrative Agent entered into an Amended and Restated Credit Agreement (the Amended Senior Credit Agreement ), which became effective December 28, 2007, that, among other things, amends certain provisions of the Original Senior Credit Agreement as set out below.

The Amended Senior Credit Agreement (i) reduced the principal amount of the U.S. Tranche A Term Loans of the Company to an aggregate principal amount of \$312.5 million, (ii) increased the principal amount of the U.S. Tranche B Term Loans of the Company to an aggregate principal amount of \$2.56 billion, (iii) created a tranche of Euro Tranche A Term Loans of the Euro Borrower in an aggregate principal amount of 350.4 (\$516.1) million and (iv) reduced the Euro Tranche B Term Loans of the Euro Borrower to an aggregate principal amount of 525.0 (\$773.3) million.

The Euro Tranche A Term Loans currently bear interest at EURIBO (determined in accordance with the Amended Senior Credit Agreement) plus 3.25% per annum. Under the terms of the Amended Senior Credit Agreement, the applicable margin over EURIBO for the Euro Tranche A Term Loans can fluctuate based on the Company's Consolidated Leverage Ratio.

The Amended Senior Credit Agreement added a prepayment premium of 1.0% of the principal amount of the U.S. Tranche B Term Loans or Euro Tranche B Term Loans prepaid in connection with voluntary and certain mandatory prepayments during the 12 months following the date of effectiveness of the Amended Senior Credit Agreement.

During the calendar year ended December 31, 2008, the company paid \$46.9 million on the U.S. Tranche A Term Loans, which included \$31.3 million of prepayments related to 2009, 52.6 (\$74.4) million on the Euro Tranche A Term Loans, which included 35.0 (\$49.6) million of prepayments related to 2009, \$51.1 million on the U.S. Tranche B Term Loans, which included \$25.6 million of prepayments related to 2009, and 10.5 (\$15.2) million on the Euro Tranche B Term Loans, which included 5.3 (\$7.4) million of prepayments related to 2009. On September 15, 2008, the outstanding borrowings under the Revolving Facility were repaid in the amount of \$300.0 million using proceeds from the Cash Convertible Notes.

At December 31, 2008 and December 31, 2007, the Company had outstanding letters of credit of \$83.6 million and \$51.3 million.

- (B) On March 1, 2007, Mylan entered into a purchase agreement relating to the sale by the Company of \$600.0 million aggregate principal amount of the Company's 1.25% Senior Convertible Notes due 2012 (the Senior Convertible Notes ). The Senior Convertible Notes bear interest at a rate of 1.25% per year, accruing from March 7, 2007. Interest is payable semiannually in arrears on March 15 and September 15 of each year, beginning September 15, 2007. The Senior Convertible Notes will mature on March 15, 2012, subject to earlier



repurchase or conversion. Holders may convert their notes subject to certain conversion provisions determined by, among others, the market price of the Company's common stock and the trading price of the Senior Convertible Notes. The Senior Convertible Notes have an initial conversion rate of 44.5931 shares of common stock per \$1,000 principal amount (equivalent to an initial conversion price of approximately \$22.43 per share), subject to adjustment, with the principal amount payable in cash and the remainder in cash or stock at the option of the Company. The accounting related to the Senior Convertible Notes will change in accordance with the adoption of FSP No. APB 14-1 (see Note 2).

On March 1, 2007, concurrently with the sale of the Senior Convertible Notes, Mylan entered into a convertible note hedge transaction, comprised of a purchased call option, and two warrant transactions with each of Merrill Lynch International, an affiliate of Merrill Lynch, and JPMorgan Chase Bank, National

**Table of Contents**

Association, London Branch, an affiliate of JPMorgan, each of which the Company refers to as a counterparty. The net cost of the transactions was \$80.6 million. The purchased call options will cover approximately 26.8 million shares of Mylan common stock, subject to anti-dilution adjustments substantially similar to the anti-dilution adjustments for the Senior Convertible Notes, which under most circumstances represents the maximum number of shares that underlie the Senior Convertible Notes. Concurrently with entering into the purchased call options, the Company entered into warrant transactions with the counterparties. Pursuant to the warrant transactions, the Company will sell to the counterparties warrants to purchase in the aggregate approximately 26.8 million shares of Mylan common stock, subject to customary anti-dilution adjustments. The warrants may not be exercised prior to the maturity of the Senior Convertible Notes, subject to certain limited exceptions.

The purchased call options are expected to reduce the potential dilution upon conversion of the Senior Convertible Notes in the event that the market value per share of Mylan common stock at the time of exercise is greater than approximately \$22.43, which corresponds to the initial conversion price of the Senior Convertible Notes. The sold warrants have an exercise price that is 60.0% higher than the price per share of \$19.50 at which the Company offered common stock in a concurrent equity offering. If the market price per share of Mylan common stock at the time of conversion of any Senior Convertible Notes is above the strike price of the purchased call options, the purchased call options will, in most cases, entitle the Company to receive from the counterparties in the aggregate the same number of shares of our common stock as the Company would be required to issue to the holder of the converted Senior Convertible Notes. Additionally, if the market price of Mylan common stock at the time of exercise of the sold warrants exceeds the strike price of the sold warrants, the Company will owe the counterparties an aggregate of approximately 26.8 million shares of Mylan common stock. The purchased call options and sold warrants may be settled for cash at the Company's election.

The purchased call options and sold warrants are separate transactions entered into by the Company with the counterparties, are not part of the terms of the Senior Convertible Notes, and will not affect the holders' rights under the Senior Convertible Notes. Holders of the Senior Convertible Notes will not have any rights with respect to the purchased call options or the sold warrants. The purchased call options and sold warrants meet the definition of derivatives under SFAS No. 133 (as amended by SFAS No. 138, *Accounting for Certain Derivative Instruments and Certain Hedging Activities* and SFAS No. 149, *Amendment of Statement 133 on Derivative Instruments and Hedging Activities*). However, because these instruments have been determined to be indexed to the Company's own stock (in accordance with the guidance of EITF Issue No. 01-6, *The Meaning of Indexed to a Company's Own Stock* (EITF Issue No. 01-6)) and have been recorded in stockholders' equity in the Company's Consolidated Balance Sheet (as determined under EITF Issue No. 00-19, *Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock* (EITF Issue No. 00-19)), the instruments are exempted from the scope of SFAS No. 133 and are not subject to the fair value provisions of that standard.

- (C) On September 15, 2008, Mylan entered into a purchase agreement relating to the sale by the Company of \$575.0 million aggregate principal amount of Cash Convertible Notes due 2015 (Cash Convertible Notes). The Cash Convertible Notes bear stated interest at a rate of 3.75% per year, accruing from September 15, 2008. The effective interest rate at December 31, 2008 is 9.5%. Interest is payable semi-annually in arrears on March 15 and September 15 of each year, beginning on March 15, 2009. The Cash Convertible Notes will mature on September 15, 2015, subject to earlier repurchase or conversion. Holders may convert their notes subject to certain conversion provisions determined by the market price of the Company's common stock, specified distributions to common shareholders, a fundamental change, and certain time periods specified in the purchase agreement. The Cash Convertible Notes have an initial conversion reference rate of 75.0751 shares of common stock per \$1,000 principal amount (equivalent to an initial conversion reference price of \$13.32 per share), subject to adjustment, with the principal amount and remainder payable in cash. The Cash Convertible Notes are

not convertible into our common stock or any other securities under any circumstance.

On September 15, 2008, concurrent with the sale of the Cash Convertible Notes, Mylan entered into a convertible note hedge and warrant transaction with certain counterparties. The net cost of the transactions was \$98.6 million. The cash convertible note hedge is comprised of purchased cash-settled call options that are expected to reduce the Company's exposure to potential cash payments required to be made by Mylan upon the

**Table of Contents**

cash conversion of the Cash Convertible Notes. Concurrent with entering into the purchased cash-settled call options, the Company entered into respective warrant transactions with the counterparties pursuant to which the Company has sold to each counterparty warrants for the purchase of shares of our common stock. Pursuant to the warrant transactions, the Company sold to the counterparties warrants to purchase in the aggregate up to approximately 43.2 million shares of Mylan common stock, subject to anti-dilution adjustments substantially similar to the anti-dilution adjustments for the Cash Convertible Notes, which under most circumstances represents the maximum number of shares that underlie the conversion reference rate for the Cash Convertible Notes. The warrants may not be exercised prior to the maturity of the Cash Convertible Notes.

Pursuant to the call option transactions, if the market price per share of the Company's common stock at the time of cash conversion of any Cash Convertible Notes is above the strike price of the purchased cash-settled call options, such call options will, in most cases, entitle us to receive from the counterparties in the aggregate the same amount of cash as we would be required to issue to the holder of the cash converted notes in excess of the principal amount thereof. The sold warrants have an exercise price of \$20.00 (which represents an exercise price of approximately 80% higher than the market price per share of \$11.10) and are net share settled, meaning that Mylan will issue a number of shares per warrant corresponding to the difference between our share price at each warrant expiration date and the exercise price.

The purchased call options and sold warrants are separate contracts entered into by us with the counterparties, are not part of the notes and do not affect the rights of holders under the Cash Convertible Notes. Holders of the Cash Convertible Notes will not have any rights with respect to the purchased call options or the sold warrants. The purchased cash-settled call options meet the definition of derivatives under SFAS No. 133. As such, the instrument is marked to market each period. In addition, the liability associated with the cash conversion feature of the Cash Convertible Notes is marked to market each period. At December 31, 2008, the \$655.4 million consists of \$419.7 million of debt (\$575.0 million face amount, net of \$155.3 million discount) and a liability with a fair value of \$235.8 million related to the bifurcated conversion feature. The purchased call options are assets recorded at their fair value of \$235.8 million within other assets in the Consolidated Balance Sheets at December 31, 2008. The warrants meet the definition of derivatives under SFAS No. 133; however, because these instruments have been determined to be indexed to the Company's own stock (in accordance with the guidance of EITF Issue No. 01-6 and have been recorded in shareholders' equity in the Company's Consolidated Balance Sheets (as determined under EITF Issue No. 00-19), the instruments are exempt from the scope of SFAS No. 133 and are not subject to the fair value provisions of that standard.

Details of the interest rates in effect at December 31, 2008 and December 31, 2007 on the outstanding borrowings under the Term Loans are in the table below:

	<b>December 31, 2008</b>		
	<b>Outstanding</b>	<b>Basis</b>	<b>Rate</b>
<i>(in thousands, except interest rates)</i>			
U.S. Tranche A Term Loans	\$ 265,625	LIBOR + 3%	6.50%
Euro Tranche A Term Loans	\$ 413,684	EURIBO + 3%	7.86%
U.S. Tranche B Term Loans			
Swapped to Fixed Rate December 2010 <sup>(1)</sup>	\$ 500,000	Fixed	6.03%
Swapped to Fixed Rate March 2010 <sup>(2)</sup>	500,000	Fixed	5.44%
Swapped to Fixed Rate December 2010 <sup>(1)</sup>	1,000,000	Fixed	7.37%
Floating Rate	504,880	LIBOR + 3.25%	5.79%

Edgar Filing: MYLAN INC. - Form 10-K

Total U.S. Tranche B Term Loans	\$ 2,504,880		
Euro Tranche B Term Loans	\$ 714,583	EURIBO + 3.25%	8.11%

(1) Designated as a cash flow hedge of expected future borrowings under the Senior Credit Agreement

(2) This interest rate swap has been extended to March 2012 at a rate of 5.38%, effective March 2010

**Table of Contents**

	<b>December 31, 2007</b>		
	<b>Outstanding</b>	<b>Basis</b>	<b>Rate</b>
<i>(in thousands, except interest rates)</i>			
U.S. Tranche A Term Loans	\$ 312,500	LIBOR + 3.25%	8.31%
Euro Tranche A Term Loans	\$ 516,127	EURIBO + 3.25%	7.75%
U.S. Tranche B Term Loans			
Swapped to Fixed Rate December 2010	\$ 1,000,000	Fixed	7.37%
Floating Rate	1,556,000	LIBOR + 3.25%	8.24%
Total U.S. Tranche B Term Loans	\$ 2,556,000		
Euro Tranche B Term Loans	\$ 773,273	EURIBO + 3.25%	7.75%

All financing fees associated with the Company's borrowings are being amortized over the life of the related debt. The total unamortized amounts of \$83.8 million and \$83.0 million are included in other assets in the Consolidated Balance Sheets at December 31, 2008 and December 31, 2007.

In conjunction with the refinancing of debt, approximately \$12.1 million of deferred financing fees were written off for the Senior Notes and Credit Facilities on October 2, 2007. There was also a tender offer premium to the Senior Notes holders made in the amount of approximately \$30.8 million. In conjunction with the financing for the former Merck Generics business acquisition, Mylan incurred approximately \$132.4 million in financing fees, of which approximately \$42.8 million were refunded from our financial institution upon the repayment of the Interim Term Loans, and an additional \$14.3 million was expensed.

At December 31, 2008 and December 31, 2007, the fair value of the Senior Convertible Notes was approximately \$444.0 million and \$545.5 million. At December 31, 2008, the fair value of the Cash Convertible Notes was approximately \$524.4 million.

Certain of the Company's debt agreements contain certain cross-default provisions.

Mandatory minimum repayments remaining on the outstanding borrowings under the term loans and convertible notes at December 31, 2008 are as follows for each of the periods ending December 31:

	<b>U.S. Tranche A Term Loans</b>	<b>Euro Tranche A Term Loans</b>	<b>U.S. Tranche B Term Loans</b>	<b>Euro Tranche B Term Loans</b>	<b>Senior Convertible Notes</b>	<b>Cash Convertible Notes</b>	<b>Total</b>
<i>(in thousands)</i>							
2009	\$	\$	\$	\$	\$	\$	\$
2010	46,875	73,003	25,560	7,292			152,730
2011	62,500	97,338	25,560	7,292			192,690
2012	78,125	121,672	25,560	7,292	600,000		832,649
2013	78,125	121,671	25,560	7,292			232,648
2014			2,402,640	685,415			3,088,055
Thereafter						655,442	655,442

Edgar Filing: MYLAN INC. - Form 10-K

Total	\$ 265,625	\$ 413,684	\$ 2,504,880	\$ 714,583	\$ 600,000	\$ 655,442	\$ 5,154,214
-------	------------	------------	--------------	------------	------------	------------	--------------

**Table of Contents****Note 13. Income Taxes**

Income tax expense (benefit) consisted of the following components:

	<b>Calendar Year Ended December 31, 2008</b>	<b>Nine Months Ended December 31, 2007</b>	<b>Fiscal Year Ended March 31, 2007</b>
<i>(dollars in thousands)</i>			
Federal:			
Current	\$ 219,370	\$ 101,659	\$ 242,434
Deferred	(90,470)	(29,343)	(46,593)
	128,900	72,316	195,841
State and Puerto Rico:			
Current	28,226	9,598	16,746
Deferred	15,978	1,903	(3,740)
	44,204	11,501	13,006
Foreign:			
Current	79,187	23,413	174
Deferred	(114,868)	(47,157)	(1,004)
	(35,681)	(23,744)	(830)
Income taxes	\$ 137,423	\$ 60,073	\$ 208,017
Pre-tax (loss) earnings			
Domestic	\$ (303,167)	\$ (413,886)	\$ 586,298
Foreign	255,344	(667,178)	(160,786)
Total	\$ (47,823)	\$ (1,081,064)	\$ 425,512
Effective tax rate	(287.4)%	(5.6)%	48.9%



**Table of Contents**

Temporary differences and carry forwards that result in the deferred tax assets and liabilities were as follows:

	<b>Calendar Year Ended December 31, 2008</b>	<b>Nine Months Ended December 31, 2007</b>	<b>Fiscal Year Ended March 31, 2007</b>
<i>(in thousands)</i>			
Deferred tax assets:			
Employee benefits	\$ 48,868	\$ 40,038	\$ 16,501
Legal matters	65,988	59,388	5,048
Accounts receivable allowances	145,579	152,123	126,191
Inventories	23,916		8,859
Deferred revenue			43,250
Investments	16,852	4,321	7,256
Other reserves	26,158	6,767	
Tax credits	4,200	3,575	3,112
Net operating losses	134,779	99,289	17,111
Convertible debt	42,733	40,514	44,100
Other	82,428	20,885	3,801
	591,501	426,900	275,229
Less: Valuation allowance	(110,194)	(76,100)	(18,355)
Total deferred tax assets	481,307	350,800	256,874
Deferred tax liabilities:			
Inventory	2,818	16,897	
Plant and equipment	77,056	67,425	40,698
Intangible assets	663,987	947,009	98,285
Investments	2,541	9,813	10,779
Other	66,190		1,890
Total deferred tax liabilities	812,592	1,041,144	151,652
Deferred tax (liabilities) assets, net	\$ (331,285)	\$ (690,344)	\$ 105,222
Classification in the Consolidated Balance Sheets:			
Deferred income tax benefit current	\$ 199,278	\$ 192,113	\$ 145,343
Deferred income tax liability current	(1,935)	(24,344)	
Deferred income tax benefit noncurrent	16,493	18,703	45,779
Deferred income tax liability noncurrent	(545,121)	(876,816)	(85,900)
Deferred tax (liability) asset, net	\$ (331,285)	\$ (690,344)	\$ 105,222



**Table of Contents**

A reconciliation of the statutory tax rate to the effective tax rate is as follows:

	<b>Calendar Year Ended  December 31, 2008</b>	<b>Nine Months Ended December 31, 2007</b>	<b>Fiscal Year Ended  March 31, 2007</b>
Statutory tax rate	35.0%	35.0%	35.0%
State and Puerto Rico income taxes and credits	(41.0)%	(0.6)%	2.8%
Research and Development tax credits	4.9%	0.3%	(0.3)%
Acquired In-Process R & D	0.0%	(41.1)%	12.1%
Effect of foreign operations	9.5%	1.8%	0.0%
Impairment of goodwill	(281.8)%	0.0%	0.0%
Other items	(14.0)%	(1.0)%	(0.7)%
Effective tax rate	(287.4)%	(5.6)%	48.9%

*Valuation Allowance*

A valuation allowance is provided when it is more likely than not that some portion or all of the deferred tax assets will not be realized. A valuation allowance has been applied to certain foreign and state deferred tax assets in the amount of \$110.2 million.

*Net Operating Losses*

As of December 31, 2008, the Company has net operating loss carryforwards for international and U.S. state income tax purposes of approximately \$1.06 billion, some of which will expire in fiscal years 2009 through 2029, while others can be carried forward indefinitely. Of these loss carryforwards, there is an amount of \$568.1 million related to state losses. A majority of the state net operating losses are attributable to Pennsylvania, where a taxpayer's use is limited to the greater of 12.5% of taxable income or \$3.0 million each taxable year. In addition, the Company has foreign net operating loss carryforwards of approximately \$494.7 million, of which \$367.6 million can be carried forward indefinitely, with the remainder expiring in years 2009 through 2023. Most of the net operating losses (foreign and state) are fully reserved.

*Acquired In-Process Research and Development*

On January 8, 2007, the Company acquired a controlling interest in Matrix, as discussed in Note 3. Of the purchase price, \$147.0 million was allocated to acquired in-process research and development and expensed. This amount is not deductible for tax purposes, and no deferred tax benefit is recorded, as required by EITF Issue No. 96-7, *Accounting for Deferred Taxes on In-Process Research and Development Activities Acquired in a Purchase Business Combination* ( EITF No. 96-7 ).

On October 2, 2007, the Company acquired the former Merck Generics business. Of the purchase price, \$1.27 billion was allocated to acquired in-process research and development and expensed. Applying the guidance in EITF No. 96-7, we determined that this amount is not deductible for tax purposes.

*Undistributed Earnings*

Operations in Puerto Rico benefit from incentive grants from the government of Puerto Rico, which partially exempt the Company from income, property and municipal taxes. In fiscal 2001, a tax grant was negotiated with the government of Puerto Rico, extending tax incentives until fiscal years 2010. This grant exempts all earnings during this grant period from tollgate tax upon repatriation of cash to the United States. In fiscal year 2007 and fiscal year 2004, \$46.5 million and \$100.0 million of cash from post-fiscal 2000 earnings was repatriated to the United States. Pursuant to the terms of our tax grant, no tollgate tax was due for these repatriations.

**Table of Contents**

*Federal Tax Credits and Ongoing IRS Examinations*

Federal tax credits result principally from qualified research and development expenditures in the United States. State tax credits are comprised mainly of awards for expansion and wage credits at the Company's manufacturing facilities and research credits awarded by certain states. State income taxes and state tax credits are shown net of the federal tax effect.

Beginning with fiscal year 2007, Mylan became a voluntary participant in the IRS Compliance Assurance Process (CAP) which results in real-time federal issue resolution. The calendar year 2007 CAP return was filed in the third quarter of calendar year 2008 and a Partial Acceptance Letter was received. Mylan did not reach agreement on a single issue that will be audited in accordance with regular IRS processes. The Company anticipates that the CAP 2007 year will be settled in the first quarter of 2009. Tax and interest continue to be accrued related to certain tax positions.

*FIN 48*

Effective April 1, 2007, the Company adopted FIN 48, which prescribes a comprehensive model for how a company should recognize, measure, present and disclose in its financial statements uncertain tax positions that the company has taken or expects to take on a tax return. Though the validity of any tax position is a matter of tax law, the body of statutory, regulatory and interpretive guidance on the application of the law is complex and often ambiguous. Because of this, whether a tax position will ultimately be sustained may be uncertain. Prior to April 1, 2007, the impact of an uncertain tax position that did not create a difference between the financial statement basis and the tax basis of an asset or liability was included in our income tax provision if it was probable the position would be sustained upon audit. The benefit of any uncertain tax position that was temporary was reflected in our tax provision if it was more likely than not that the position would be sustained upon audit. Prior to the adoption of FIN 48, Mylan recognized interest expense based on our estimates of the ultimate outcomes of the uncertain tax positions.

Under FIN 48, the impact of an uncertain tax position that is more likely than not of being sustained upon audit by the relevant taxing authority must be recognized at the largest amount that is more likely than not to be sustained. No portion of an uncertain tax position will be recognized if the position has less than a 50% likelihood of being sustained. Also, under FIN 48, interest expense is recognized on the full amount of deferred benefits for uncertain tax positions.

As of December 31, 2008 and December 31, 2007, the Company's Consolidated Balance Sheet reflects a liability for unrecognized tax benefits of \$166.5 million and \$77.6 million. Accrued interest and penalties included in the Consolidated Balance Sheet were \$34.8 million and \$24.4 million as of December 31, 2008 and December 31, 2007. For the calendar year ended December 31, 2008 and the nine months ended December 31, 2007, Mylan recognized \$8.9 million and \$1.8 million for interest expense related to uncertain tax positions.

The major state taxing jurisdictions applicable to the Company remain open from fiscal year 2005 through fiscal year 2008. The major taxing jurisdictions for the Company internationally remain open from 2002 through 2008 some of which are indemnified by Merck KGaA for tax assessments.

**Table of Contents**

A reconciliation of the unrecognized tax benefits from December 31, 2007 to December 31, 2008 and from March 31, 2007 to December 31, 2007 is as follows:

	<b>Unrecognized Tax Benefits</b>
<i>(in thousands)</i>	
Balance at December 31, 2007	\$ 77,600
Additions for current year tax positions	49,169
Additions for prior year tax positions	538
Reductions for prior year tax positions	(3,313)
Settlements	
Reductions related to expirations of statute of limitations	(4,819)
Addition due to cumulative adjustment	47,338
Balance at December 31, 2008	\$ 166,513

	<b>Unrecognized Tax Benefits</b>
<i>(in thousands)</i>	
Balance at March 31, 2007	\$ 42,900
Additions for current year tax positions	5,700
Additions for prior year tax positions	4,400
Reductions for prior year tax positions	(3,300)
Settlements	(10,500)
Reductions related to expirations of statute of limitations	(1,200)
Addition due to cumulative adjustment	39,600
Balance at December 31, 2007	\$ 77,600

In accordance with Mylan's accounting policy, both before and after adoption of FIN 48, interest expense and penalties related to income taxes are included in the tax provision.

It is anticipated that the amount of unrecognized tax benefits will decrease in the next twelve months. The Company foresees issues involving purchase accounting, state tax audits and the expiration of certain statutes of limitations having a significant impact on its results of operations, cash flows and financial position. We expect the range of the decrease of our existing reserve to be between \$20.0 million and \$35.0 million. We do not anticipate significant increases to the reserve within the next twelve months.

**Note 14. Preferred and Common Stock**

The Company entered into a Rights Agreement (the "Rights Agreement") with American Stock Transfer & Trust Company, as rights agent, to provide the Board with sufficient time to assess and evaluate any takeover bid and explore and develop a reasonable response. Effective November 1999, the Rights Agreement was amended to

eliminate certain limitations on the Board's ability to redeem or amend the rights to permit an acquisition and also to eliminate special rights held by incumbent directors unaffiliated with an acquiring shareholder. The Rights Agreement will expire on August 13, 2014 unless it is extended or such rights are earlier redeemed or exchanged.

In fiscal year 1985, the Board of Directors (the Board) authorized 5,000,000 shares of \$0.50 par value preferred stock. Prior to November 19, 2007, no preferred stock had been issued. On November 19, 2007, the Company completed public offerings of 2,139,000 shares of 6.5% mandatory convertible preferred stock (preferred stock) at \$1,000 per share, as well as an offering of 55,440,000 shares of common stock at \$14.00 per share, pursuant to a shelf registration statement previously filed with the Securities and Exchange Commission.

**Table of Contents**

The preferred stock will pay, when declared by the Board of Directors, dividends at a rate of 6.50% per annum on the liquidation preference of \$1,000 per share, payable quarterly in arrears in cash, shares of Mylan common stock or a combination thereof at the Company's election. The first dividend date was February 15, 2008. Each share of preferred stock will automatically convert on November 15, 2010, into between 58.5480 shares and 71.4286 shares of the Company's common stock, depending on the average daily closing price per share of our common stock over the 20 trading day period ending on the third trading day prior to November 15, 2010. The conversion rate will be subject to anti-dilution adjustments in certain circumstances. Holders may elect to convert at any time at the minimum conversion rate of 58.5480 shares of common stock for each share of preferred stock.

During the calendar year ended December 31, 2008, the Company paid dividends of \$137.5 million on the preferred stock. On January 29, 2009, the Company announced that a quarterly dividend of \$16.25 per share was declared, payable on February 17, 2009, to the holders of preferred stock of record as of February 1, 2009. Accordingly, Mylan recorded a dividend payable of \$17.5 million and \$16.0 million at December 31, 2008 and December 31, 2007. The Company expects to pay dividends in cash on February 15, May 15, August 15, and November 15 (or, as applicable, the next business day) of each year prior to November 15, 2010. Under certain circumstances, the Company may not be allowed to pay dividends in cash. If this were to occur, any unpaid dividend would be payable in shares of common stock on November 15, 2010 based on the market value of common stock at that time.

**Note 15. Stock-Based Incentive Plan**

Mylan's shareholders approved the *2003 Long-Term Incentive Plan* on July 25, 2003, and approved certain amendments on July 28, 2006 and April 25, 2008 (as amended, the *2003 Plan*). Under the 2003 Plan, 37,500,000 shares of common stock are available for issuance to key employees, consultants, independent contractors and non-employee directors of Mylan through a variety of incentive awards, including: stock options, stock appreciation rights, restricted shares and units, performance awards, other stock-based awards and short-term cash awards. Awards are granted at the fair value of the shares underlying the options at the date of the grant, generally become exercisable over periods ranging from three to four years, and generally expire in ten years. In the 2003 Plan, no more than 5,000,000 shares may be issued as restricted shares, restricted units, performance shares and other stock-based awards.

Upon approval of the 2003 Plan, the *1997 Incentive Stock Option Plan* (the *1997 Plan*) was frozen, and no further grants of stock options will be made under that plan. However, there are stock options outstanding from the 1997 Plan, expired plans and other plans assumed through acquisitions.



**Table of Contents**

The following table summarizes stock option activity:

	<b>Number of Shares Under Option</b>	<b>Weighted Average Exercise Price per Share</b>
Outstanding at March 31, 2006	21,358,670	\$ 15.16
Options granted	1,139,400	21.65
Options exercised	(4,053,061)	12.18
Options forfeited	(797,281)	17.28
Outstanding at March 31, 2007	17,647,728	16.17
Options granted	4,303,792	15.91
Options exercised	(459,836)	13.18
Options forfeited	(661,148)	17.51
Outstanding at December 31, 2007	20,830,536	16.15
Options granted	4,180,133	11.46
Options exercised	(107,707)	10.20
Options forfeited	(1,479,921)	16.64
Outstanding at December 31, 2008	23,423,041	\$ 15.32
Vested and expected to vest at December 31, 2008	22,852,133	\$ 15.35
Options exercisable at December 31, 2008	15,048,569	\$ 15.86

As of December 31, 2008, options outstanding, options vested and expected to vest, and options exercisable had average remaining contractual terms of 5.93 years, 5.86 years and 4.49 years, respectively. Also at December 31, 2008, options outstanding, options vested and expected to vest and options exercisable had aggregate intrinsic values of \$0.1 million, \$0.1 million and \$0.05 million, respectively.

A summary of the status of the Company's nonvested restricted stock and restricted stock unit awards is presented below:

<b>Restricted Stock Awards</b>	<b>Number of Restricted Stock Awards</b>	<b>Weighted Average Grant-Date Fair Value</b>
Nonvested at December 31, 2007	1,295,347	\$ 16.95
Granted	1,699,856	11.30
Released	(367,939)	15.57
Forfeited	(83,916)	14.22

Nonvested at December 31, 2008	2,543,348	\$	13.46
--------------------------------	-----------	----	-------

Of the 1,699,856 awards granted during the calendar year ended December 31, 2008, 601,801 vest ratably over 3 years, 750,246 vest in three years, 262,388 vest one-third immediately with the remaining vesting ratably over two years, 56,421 vest in one year, and the remaining 29,000 vest ratably over four years.

As of December 31, 2008, the Company had \$40.2 million of total unrecognized compensation expense, net of estimated forfeitures, related to all of its stock-based awards, which will be recognized over the remaining weighted average period of 1.72 years. The total intrinsic value of stock-based awards exercised and restricted stock units converted during the calendar year ended December 31, 2008 and the nine months ended December 31, 2007 was \$4.7 million and \$3.3 million.

With respect to options granted under the Company's stock-based compensation plans, the fair value of each option grant was estimated at the date of grant using the Black-Scholes option pricing model. Black-Scholes utilizes

**Table of Contents**

assumptions related to volatility, the risk-free interest rate, the dividend yield and employee exercise behavior. Expected volatilities utilized in the model are based mainly on the historical volatility of the Company's stock price and other factors. The risk-free interest rate is derived from the U.S. Treasury yield curve in effect at the time of grant. The model incorporates exercise and post-vesting forfeiture assumptions based on an analysis of historical data. The expected lives of the grants are derived from historical and other factors. The assumptions used are as follows:

	<b>Calendar Year Ended December 31, 2008</b>	<b>Nine Months Ended December 31, 2007</b>	<b>Fiscal Year Ended March 31, 2007</b>
Volatility	31.0%	30.8%	34.0%
Risk-free interest rate	2.2%	4.6%	4.8%
Dividend yield	0.0%	0.0%	1.1%
Expected term of options (in years)	4.5	5.0	4.5
Forfeiture rate	5.5%	3.0%	3.0%
Weighted average grant date fair value per option	\$ 3.37	\$ 5.60	\$ 6.90

In addition, Matrix has a stock option plan under which 3,288,965 options have been granted to its employees as of March 31, 2007. These grants were made prior to the acquisition of Matrix by Mylan. During the calendar year ended December 31, 2008 and the nine-month period ended December 31, 2007, no options were granted under the Matrix plan. As of December 31, 2008, there were 1.9 million options exercisable.

**Note 16. Employee Benefits***Defined Benefit Plans*

The Company sponsors various defined benefit pension plans in several countries, most of which were assumed in the acquisition of the former Merck Generics business. Benefit formulas are based on varying criteria on a plan by plan basis. Mylan's policy is to fund domestic pension liabilities in accordance with the minimum and maximum limits imposed by the Employee Retirement Income Security Act of 1974 (ERISA) and Federal income tax laws. 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 amounts accrued related to these benefits were \$48.3 million and \$37.5 million at December 31, 2008 and December 31, 2007.

The Company has a plan covering certain employees in the United States and Puerto Rico to provide for limited reimbursement of postretirement supplemental medical coverage. In addition, in December 2001, the Supplemental Health Insurance Program for Certain Officers of the Company was adopted to provide full postretirement medical coverage to certain officers and their spouses and dependents. The program was terminated in April 2006, except with respect to certain individuals. These plans generally provide benefits to employees who meet minimum age and service requirements. The amounts accrued related to these benefits were not material at December 31, 2008 and December 31, 2007.

Effective March 31, 2007, the Company adopted SFAS No. 158, *Employers' Accounting for Defined Benefit Pension and Other Postretirement Plans, an amendment of FASB Statements No. 87, 88, 106, and 132(R)* (SFAS No. 158). The provisions of SFAS No. 158 require that the funded status of the Company's pension plans and the benefit obligations of our post-retirement benefit plans be recognized in the balance sheet. SFAS No. 158 did not change the measurement or recognition of these plans, although it did require that plan assets and benefit obligations be measured

as of the balance sheet date. The Company has historically measured the plan assets and benefit obligations as of the balance sheet date. Under SFAS No. 158, changes in the funded status will be recognized in other comprehensive income until they are amortized as a component of net periodic benefit cost. The adjustments to adopt SFAS No. 158 were not material and were recorded as a component of accumulated other comprehensive income at the adoption date.

**Table of Contents***Defined Contribution Plans*

The Company sponsors defined contribution plans covering certain of its employees in the United States and Puerto Rico, as well as certain employees in a number of countries related to the former Merck Generics business acquisition. Its domestic defined contribution plans consist primarily of a 401(k) retirement plan with a profit sharing component for non-union employees and a 401(k) retirement plan for union employees. Profit sharing contributions are made at the discretion of the Board. Its non-domestic plans vary in form depending on local legal requirements. The Company's contributions are based upon employee contributions, service hours, or pre-determined amounts depending upon the plan. Obligations for contributions to defined contribution plans are recognized as expense in the Consolidated Statements of Operations when they are due. Total employer contributions to defined contribution plans were \$20.4 million for the calendar year ended December 31, 2008, \$12.2 million for the nine months ended December 31, 2007 and \$16.5 million for the fiscal year ended March 31, 2007.

Additionally, Matrix has several defined contribution plans covering certain employees and a Provident Fund which, in accordance with Indian Law, covers all employees located in India.

*Other Benefit Arrangements*

The Company provides supplemental life insurance benefits to certain management employees. Such benefits require annual funding and may require accelerated funding in the event that the Company would experience a change in control.

The production and maintenance employees at the Company's manufacturing facilities in Morgantown, West Virginia, are covered under a collective bargaining agreement that expires in April 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. These employees represented approximately 13% and 17% of the Company's total permanent workforce at December 31, 2008 and December 31, 2007.

**Note 17. Segment Information**

Mylan has three reportable segments: the Generics Segment, the Specialty Segment, and the Matrix Segment. The Generics Segment primarily develops, manufactures, sells and distributes generic or branded generic pharmaceutical products in tablet, capsule or transdermal patch form. The Specialty Segment engages mainly in the manufacture and sale of branded specialty nebulized and injectable products. The Matrix Segment engages mainly in the manufacture and sale of APIs and FDFs and the distribution of certain branded generic products. Additionally, certain general and administrative expenses, as well as litigation settlements, non-cash impairment charges and other expenses not attributable to segments are reported in Corporate/Other.

The Company's chief operating decision maker evaluates the performance of its reportable segments based on total revenues and segment profitability. For the Generics, Specialty and Matrix Segments, segment profitability represents segment gross profit less direct research and development expenses and direct selling, general and administrative expenses. Amortization of intangible assets as well as other purchase accounting related items including the write-off of in-process research and development and the amortization of the inventory step-up, non-cash impairment charges and revenue related to the sale of Bystolic product rights are excluded from segment profitability. The Company does not report depreciation expense, total assets and capital expenditures by segment, as such information is not used by the chief operating decision maker.

The accounting policies of the segments are the same as those described in Note 2 to Consolidated Financial Statements. Intersegment revenues are accounted for at current market values.

The table below presents segment information for the periods identified and provides a reconciliation of segment information to total consolidated information.

**Table of Contents****Calendar Year Ended**

<b>December 31, 2008</b> <i>(in thousands)</i>	<b>Generics Segment</b>	<b>Specialty Segment</b>	<b>Matrix Segment</b>	<b>Corporate/Other<sup>(1)</sup></b>	<b>Consolidated</b>
Total revenues					
Third party	\$ 3,907,518	\$ 385,963	\$ 376,007	\$ 468,097	\$ 5,137,585
Intersegment	1,798	31,278	68,813	(101,889)	
Total	3,909,316	417,241	444,820	366,208	\$ 5,137,585
Segment profitability	\$ 969,929	\$ 36,649	\$ 25,033	\$ (733,726)	\$ 297,885

**Nine Months Ended**

<b>December 31, 2007</b>	<b>Generics Segment</b>	<b>Specialty Segment</b>	<b>Matrix Segment</b>	<b>Corporate/Other<sup>(1)</sup></b>	<b>Consolidated</b>
Total revenues					
Third party	\$ 1,812,404	\$ 102,126	\$ 264,231	\$	\$ 2,178,761
Intersegment	563	3,401	29,547	(33,511)	
Total	1,812,967	105,527	293,778	(33,511)	\$ 2,178,761
Segment profitability	\$ 590,363	\$ 18,880	\$ 18,120	\$ (1,615,628)	\$ (988,265)

**Fiscal Year Ended**

<b>March 31, 2007</b>	<b>Generics Segment</b>	<b>Specialty Segment</b>	<b>Matrix Segment</b>	<b>Corporate/Other<sup>(1)</sup></b>	<b>Consolidated</b>
Total revenues					
Third party	\$ 1,532,407	\$	\$ 79,412	\$	\$ 1,611,819
Intersegment			16,389	(16,389)	
Total	1,532,407		95,801	(16,389)	\$ 1,611,819
Segment profitability	\$ 712,685	\$	\$ 8,578	\$ (293,709)	\$ 427,554

<sup>(1)</sup> Includes corporate general and administrative expenses, litigation settlements, intercompany eliminations, revenue related to the sale of Bystolic product rights, amortization of intangible assets and certain purchase accounting items (such as the write-off of in-process research and development and the amortization of the inventory step-up), non-cash impairment charges, and other expenses not directly attributable to segments.

The Company's consolidated net revenues are generated via the sale of products in the following therapeutic categories:

	<b>Calendar Year Ended December 31, 2008</b>	<b>Nine Months Ended December 31, 2007</b>	<b>Fiscal Year Ended March 31, 2007</b>
<i>(in thousands)</i>			
Allergy	\$ 219,308	\$ 28,301	\$
Anti-infective Agents	455,513	166,383	60,768
Cardiovascular	889,523	587,020	463,610
Central Nervous System	1,235,340	584,466	579,814
Dermatology	72,944	44,718	58,066
Endocrine and Metabolic	408,384	198,875	133,967
Gastrointestinal	357,489	149,804	59,655
Renal and Genitourinary	209,374	122,484	148,494
Respiratory Agents	310,993	71,167	7,810
Other <sup>(1)</sup>	472,369	209,725	74,763
	\$ 4,631,237	\$ 2,162,943	\$ 1,586,947



**Table of Contents**

(1) Other consists of numerous therapeutic classes, none of which individually exceeds 5% of consolidated net revenues.

*Geographic Information*

The Company's principal markets are North America, EMEA, and Asia Pacific. Net revenues are classified based on the geographic location of the customers and are as follows:

	<b>Calendar Year Ended December 31, 2008</b>	<b>Nine Months Ended December 31, 2007</b>	<b>Fiscal Year Ended March 31, 2007</b>
<i>(in thousands)</i>			
Net third-party revenues			
The Americas			
United States	\$ 2,075,308	\$ 1,342,564	\$ 1,506,419
Other Americas	163,512	68,117	2,622
Europe <sup>(1)</sup>	1,755,807	508,549	50,958
Asia	636,610	243,713	26,948
	\$ 4,631,237	\$ 2,162,943	\$ 1,586,947

(1) Sales in France consisted of 16% of consolidated net revenues for the calendar year ended December 31, 2008.

**Note 18. Commitments**

The Company leases certain property under various operating lease arrangements that expire over the next seven years. These leases generally provide the Company with the option to renew the lease at the end of the lease term. For the calendar year ended December 31, 2008, the nine months ended December 31, 2007 and the fiscal year ended March 31, 2007, the Company made lease payments of \$33.0 million, \$9.3 million and \$3.9 million, respectively.

Future minimum lease payments under these commitments are as follows:

<b>December 31,</b> <i>(in thousands)</i>	<b>Operating Leases</b>
2009	\$ 30,081
2010	24,178
2011	19,230
2012	12,814
2013	10,128
Thereafter	57,905
	\$ 154,336

The Company has entered into various product licensing and development agreements. In some of these arrangements, the Company provides 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 \$39.3 million would be paid subsequent to December 31, 2008.

The Company has also 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

**Table of Contents**

payments under certain circumstances. Additionally, the Company has split-dollar life insurance agreements with certain retired executives.

In the normal course of business, Mylan periodically enters into employment, legal settlement and other agreements which incorporate indemnification provisions. While the maximum amount to which Mylan may be exposed under such agreements cannot be reasonably estimated, the Company maintains insurance coverage, which management believes will effectively mitigate the Company's obligations under these indemnification provisions. No amounts have been recorded in the Consolidated Financial Statements with respect to the Company's obligations under such agreements.

**Note 19. Contingencies****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.

*Omeprazole*

On May 17, 2000, Mylan Pharmaceuticals Inc. ( MPI ) filed an ANDA seeking approval from the FDA to manufacture, market and sell omeprazole delayed-release capsules and on August 8, 2000 made Paragraph IV certifications to several patents owned by AstraZeneca PLC ( AstraZeneca ) that were listed in the FDA's Orange Book. On September 8, 2000, AstraZeneca filed suit against MPI and Mylan in the U.S. District Court for the Southern District of New York alleging infringement of several of AstraZeneca's patents. On May 29, 2003, the FDA approved MPI's ANDA for the 10 mg and 20 mg strengths of omeprazole delayed-release capsules, and, on August 4, 2003, Mylan announced that MPI had commenced the sale of omeprazole 10 mg and 20 mg delayed-release capsules. AstraZeneca then amended the pending lawsuit to assert claims against Mylan and MPI and filed a separate lawsuit against MPI's supplier, Esteve Quimica S.A. ( Esteve ), for unspecified money damages and a finding of willful infringement. MPI has certain indemnity obligations to Esteve in connection with this litigation. On May 31, 2007, the district court ruled in Mylan's and Esteve's favor by finding that the asserted patents were not infringed by Mylan's/Esteve's products. On July 18, 2007, AstraZeneca appealed the decision to the United States Court of Appeals for the Federal Circuit. On June 10, 2008, the appellate court issued a judgment and decision affirming the district court's finding of noninfringement and the mandate was issued on July 1, 2008.

*Lorazepam and Clorazepate*

On June 1, 2005, a jury verdict was rendered against Mylan, 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, some or all of which may be subject to

**Table of Contents**

indemnification obligations by Mylan. Plaintiffs are also seeking an award of attorneys' fees and litigation costs in unspecified amounts and prejudgment interest of approximately \$9.0 million. The Company and its co-defendants have appealed to the U.S. Court of Appeals for the D.C. Circuit. The appeals have been held in abeyance pending a ruling on the motion for prejudgment interest. 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, 2008) and an irrevocable letter of credit for \$34.5 million issued under the Senior Credit Agreement. On October 27, 2008, a U.S. magistrate judge issued a report recommending the granting of plaintiffs' motion for prejudgment interest. The report also recommends requiring the surety bond amount to be increased to include prejudgment interest. Mylan has submitted objections to the magistrate judge's recommendations and now pending is the district court's determination of whether to accept or reject those recommendations. If the magistrate's recommendations on prejudgment interest are accepted, Mylan intends to contest these rulings as part of its pending appeal.

*Pricing and Medicaid Litigation*

On June 26, 2003, MPI and UDL received requests from the U.S. House of Representatives Energy and Commerce Committee (the Committee) seeking information about certain products sold by MPI and UDL Laboratories Inc. (UDL) in connection with the Committee's investigation into pharmaceutical reimbursement and rebates under Medicaid. MPI and UDL cooperated with this inquiry and provided information in response to the Committee's requests in 2003. Several states' attorneys general (AG) have also sent letters to MPI, UDL and Mylan Bertek Pharmaceuticals Inc., demanding that those companies retain documents relating to Medicaid reimbursement and rebate calculations pending the outcome of unspecified investigations by those AGs into such matters. In addition, in July 2004, Mylan received subpoenas from the AGs of California and Florida in connection with civil investigations purportedly related to price reporting and marketing practices regarding various drugs. As noted below, both California and Florida subsequently filed suits against Mylan, and the Company believes any further requests for information and disclosures will be made as part of that litigation.

Beginning in September 2003, Mylan, MPI and/or UDL, together with many other pharmaceutical companies, have been named in civil lawsuits filed by state 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. 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 an unspecified amount in money damages, civil penalties and/or treble damages, counsel fees and costs, and injunctive relief. In each of these matters Mylan, MPI and/or UDL either have either moved to dismiss the complaints or have answered the complaints denying liability. Mylan and its subsidiaries intend to defend each of these actions vigorously.

In May 2008, an amended complaint was filed in the U.S. District Court for the District of Massachusetts by a 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 recovery of any and all alleged overpayment of the federal share under the Medicaid program. Mylan has moved to dismiss the complaint and intends to defend the action vigorously.

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 involves whether MPI and UDL

**Table of Contents**

may have violated the False Claims Act or other laws by classifying certain authorized generics launched in the 1990 s and early 2000 s as non-innovator rather than innovator drugs for purposes of Medicaid and other federal healthcare programs until 2005. MPI and UDL deny the government s allegations and deny that they engaged in any wrongful conduct. Based on our understanding of the government s allegations, the alleged difference in rebates for the MPI and UDL products currently at issue may be up to approximately \$100.0 million, which includes interest. Remedies under the False Claims Act could include treble damages and penalties. MPI and UDL have been cooperating fully with the government s investigation and are currently in discussions with the government about a possible resolution of the matter. Additionally, the Company believes that it has contractual and other rights to recover from the innovator a substantial portion of any payments that MPI and UDL may remit to the government. The Company has not recorded any amounts in the consolidated financial statements related to this matter.

Dey, L.P. is a defendant currently in lawsuits brought by the state AG s of Arizona, California, Florida, Illinois, Iowa, Kansas, Kentucky, Pennsylvania, South Carolina (on behalf of the state and the state health plan), Utah and Wisconsin and 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 most of these class actions, which has been preliminarily approved by the court. Additionally, the U.S. federal government filed a claim against Dey, L.P. in August 2006. These cases all generally allege that Dey falsely reported certain price information concerning certain drugs marketed by Dey. Dey intends to defend each of these actions vigorously. In conjunction with the former Merck Generics business acquisition by Mylan, Mylan is entitled to indemnification by Merck KGaA for these Dey pricing related suits.

The Company has approximately \$118.6 million recorded in other liabilities related to the price-related litigation involving Dey. As stated above, in conjunction with the former Merck Generics business acquisition, Mylan is entitled to indemnification from Merck KGaA under the Share Purchase Agreement. As a result, the Company has recorded approximately \$119.7 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 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 action are pending, with the exception of the third-party payor action, in which Mylan s response to the complaint is not due until the motions filed in the other cases have been decided. 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 MTI 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 is cooperating 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*

In March 2004, Mylan Inc. and MPI, along with Dr. Reddy's Laboratories, Inc., were named in a civil lawsuit filed in the Northern District of Georgia by UCB Society Anonyme and UCB Pharma, Inc. ( UCB ) alleging infringement of U.S. Patent No. 4,943,639 relating to levetiracetam tablets. This litigation was settled in October 2007. Under the terms of the settlement, Mylan was granted the right to market 250 mg, 500 mg, and 750 mg levetiracetam tablets in the United States beginning on November 1, 2008, provided that UCB obtained pediatric exclusivity for its product and Mylan obtained final approval for its ANDA from the FDA. Pediatric exclusivity has



**Table of Contents**

been granted. In addition, by letter dated November 19, 2007, Mylan was notified by the FTC of an investigation relating to the settlement of the levetiracetam patent litigation. In its letter, the FTC requested certain information from Mylan pertaining to the patent litigation and the settlement thereof. On April 9, 2008, the FTC issued a civil investigative demand requesting additional information from Mylan relating to the investigation. Mylan is cooperating fully with the government's investigation and has complied with all requests for information. Mylan launched its 250 mg, 500 mg, and 750 mg levetiracetam tablet products in November 2008.

*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 is 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, approximately 198 lawsuits have been filed against Mylan, UDL and Actavis pertaining to the recall. An adverse outcome in these lawsuits or the inability or denial of Actavis to pay on an indemnified claim could have a materially adverse effect on our financial position and results of operations.

*Pioglitazone*

On February 21, 2006, a district court in the United States District Court for the Southern District of New York held that Mylan, MPI and UDL's pioglitazone ANDA product infringed a patent asserted against them by Takeda Pharmaceuticals North America, Inc. and Takeda Chemical Industries, Ltd (hereinafter, "Takeda") and that the patent was enforceable. That same court also held that Alphapharm Pty, Ltd and Genpharm, Inc.'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. 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. Although the required amounts have been paid, Mylan and Alphapharm/Genpharm intend to continue to challenge the exceptional case findings by filing petitions for writ of certiorari with the United States Supreme Court.

*Litigation related to the former Merck Generics Business*

Generics UK Ltd. was accused of having been involved in pricing agreements pertaining to certain drugs during the years 1996 to 2000. Generics UK Ltd. was able to settle civil claims for damages brought by the National Health Service in England, and Wales, and health authorities in Scotland and Northern Ireland out of court, without any admission of liability. In addition to these civil claims, in 2006 criminal proceedings were filed in Southwark Crown Court against Generics UK Ltd. and other companies, as well as against a number of individuals who were alleged to be responsible for decision making in the companies. In early 2008, the House of Lords ruled that a price fixing cartel was not at the relevant times a criminal offense. The case was remanded back to the Crown Court for the prosecution to make an application to amend the indictment. On July 11, 2008, the Crown Court refused to allow the prosecution's application, quashed the indictment and denied the prosecution's application for permission to appeal. On July 17, 2008, the prosecution applied to the Court of Appeal (Criminal Division) for permission to appeal. On December 3, 2008, the Court of Appeal denied the prosecution's application for permission to appeal. Accordingly, all civil and criminal proceedings relating to the above described pricing agreements have now been either terminated or resolved.

*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 former Merck Generics business acquisition. While it is not possible 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 or results of operations.

**Table of Contents**

**Management's Report on Internal Control over Financial Reporting**

Management of Mylan Inc. (the Company) is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with accounting principles generally accepted in the United States of America. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions or that the degree of compliance with the policies or procedures may deteriorate.

In conducting the December 31, 2008 assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in *Internal Control - Integrated Framework* (COSO). As a result of this assessment and based on the criteria in the COSO framework, management has concluded that, as of December 31, 2008, the Company's internal control over financial reporting was effective.

Our independent registered public accounting firm, Deloitte & Touche LLP, has audited this internal control over financial reporting. Deloitte & Touche LLP's opinion on the Company's internal control over financial reporting appears on page 122 of this Form 10-K.

**Table of Contents**

**Report of Independent Registered Public Accounting Firm**

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

We have audited the accompanying consolidated balance sheets of Mylan Inc. and subsidiaries (the Company) as of December 31, 2008 and 2007, and the related consolidated statements of operations, shareholders' equity, and cash flows for the year ended December 31, 2008, the nine months ended December 31, 2007 and the year ended March 31, 2007. Our audits also included the consolidated financial statement schedule included in Item 15. These financial statements, and financial statement schedule, are the responsibility of the Company's management. Our responsibility is to express an opinion on the financial statements and financial statement schedule based on our audits.

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

In our opinion, such consolidated financial statements present fairly, in all material respects, the financial position of Mylan Inc. and subsidiaries as of December 31, 2008 and 2007, and the results of their operations and their cash flows for the year ended December 31, 2008, the nine months ended December 31, 2007, and the year ended March 31, 2007, in conformity with accounting principles generally accepted in the United States of America. Also, in our opinion, such consolidated financial statement schedule, when considered in relation to the basic consolidated financial statements taken as a whole, presents fairly, in all material respects, the information set forth therein.

As discussed in Note 13 to the consolidated financial statements, effective April 1, 2007, the Company adopted FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes – an Interpretation of FASB Statement No. 109*.

As discussed in Note 1 to the consolidated financial statements, effective October 2, 2007, the Company changed its fiscal year to begin on January 1 and end on December 31.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the Company's internal control over financial reporting as of December 31, 2008, based on the criteria established in *Internal Control – Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated February 16, 2009 expressed an unqualified opinion on the Company's internal control over financial reporting.

Pittsburgh, Pennsylvania  
February 16, 2009

**Table of Contents**

**Report of Independent Registered Public Accounting Firm**

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

We have audited the internal control over financial reporting of Mylan Inc. and subsidiaries (the Company) as of December 31, 2008, based on criteria established in *Internal Control – Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit.

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

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

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

In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2008, based on the criteria established in *Internal Control – Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated financial statements and consolidated financial statement schedule as of and for the year ended December 31, 2008 of the Company and our report dated February 16, 2009 expressed an unqualified opinion on those financial statements and financial statement schedule.

Pittsburgh, Pennsylvania  
February 16, 2009

**Table of Contents****Mylan Inc.  
Supplementary Financial Information****Quarterly Financial Data**

(unaudited, in thousands, except per share data)

**Calendar Year Ended December 31, 2008**

	<b>March 31, 2008<sup>(3)</sup></b>	<b>Three-Month Period Ended June 30, 2008</b>	<b>September 30, 2008<sup>(4)</sup></b>	<b>December 31, 2008</b>
Total revenues	\$ 1,074,461	\$ 1,203,122	\$ 1,656,848	\$ 1,203,154
Gross profit	350,221	414,210	911,137	394,653
Net (loss) earnings available to common shareholders	(443,893)	(8,366)	171,999	(39,990)
(Loss) earnings per share <sup>(1)</sup> :				
Basic	\$ (1.46)	\$ (0.03)	\$ 0.56	\$ (0.13)
Diluted	\$ (1.46)	\$ (0.03)	\$ 0.45	\$ (0.13)
Share prices <sup>(2)</sup> :				
High	\$ 15.40	\$ 13.35	\$ 14.02	\$ 11.28
Low	\$ 10.33	\$ 11.40	\$ 10.85	\$ 5.77

**Nine Months Ended December 31, 2007**

	<b>June 30, 2007</b>	<b>Three-Month Period Ended September 30, 2007</b>	<b>December 31, 2007<sup>(5)</sup></b>
Total revenues	\$ 546,321	\$ 477,091	\$ 1,155,349
Gross profit	296,708	221,641	356,099
Net (loss) earnings available to common shareholders	79,727	149,827	(1,383,577)
(Loss) earnings per share <sup>(1)</sup> :			
Basic	\$ 0.32	\$ 0.60	\$ (5.04)
Diluted	\$ 0.32	\$ 0.60	\$ (5.04)
Share prices <sup>(2)</sup> :			
High	\$ 22.64	\$ 18.19	\$ 16.87
Low	\$ 18.19	\$ 14.00	\$ 13.25

(1) The sum of earnings per share for the quarters may not equal earnings per share for the total year due to changes in the average number of common shares outstanding and the effect of the if-converted method related to our outstanding mandatorily redeemable preferred stock.

(2)

Closing prices for all dates prior to December 29, 2008 are as reported on the New York Stock Exchange. Closing prices for December 31, 2008 are as reported on The NASDAQ Stock Market.

- (3) The results for the three months ended March 31, 2008, include a \$385.0 million non-cash goodwill impairment charge.
- (4) The results for the three months ended September 30, 2008, include \$455.0 million of revenue and gross profit related to the sale of the Bystolic product rights.
- (5) The results for the three months ended December 31, 2007, include the results of the former Merck Generics business since its acquisition on October 2, 2007, and certain purchase accounting adjustments, including \$1.27 billion related to acquired in-process research and development.



**Table of Contents**

**ITEM 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure**

None.

**ITEM 9A. Controls and Procedures**

An evaluation was performed under the supervision and with the participation of the Company's management, including the Chief Executive Officer and the Chief Financial Officer, of the effectiveness of the design and operation of the Company's disclosure controls and procedures as of December 31, 2008. Based upon that evaluation, the Chief Executive Officer and the Chief Financial Officer concluded that the Company's disclosure controls and procedures were effective.

Management has not identified any changes in the Company's internal control over financial reporting that occurred during the quarter that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

Management's Report on Internal Control over Financial Reporting is on page 120. The effectiveness of the Company's internal control over financial reporting as of December 31, 2008, has been audited by Deloitte & Touche LLP, an independent registered public accounting firm, as stated in their report which is on pages 122.

**ITEM 9B. Other Information**

None.

**PART III**

**ITEM 10. Directors, Executive Officers and Corporate Governance**

Certain information required by this item will be set forth under the captions "Item I Election of Directors," "Executive Officers" and "Security Ownership of Certain Beneficial Owners and Management Section 16(a) Beneficial Ownership Reporting Compliance" in our 2009 Proxy Statement and is incorporated herein by reference.

*Code of Ethics*

The Company has adopted a Code of Ethics that applies to our Chief Executive Officer, Chief Financial Officer and Corporate Controller. This Code of Ethics is posted on the Company's Internet website at [www.mylan.com](http://www.mylan.com). The Company intends to post any amendments to or waivers from the Code of Ethics on that website.

**ITEM 11. Executive Compensation**

The information required by Item 11 will be set forth under the caption "Executive Compensation" in our 2009 Proxy Statement and is incorporated herein by reference.

**ITEM 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters**

The information required by Item 12 will be set forth under the captions "Security Ownership of Certain Beneficial Owners and Management" and "Executive Compensation Equity Compensation Plan Information" in our 2009 Proxy

Statement and is incorporated herein by reference.

**ITEM 13. Certain Relationships and Related Transactions, and Director Independence**

The information required by Item 13 will be set forth under the caption Certain Relationships and Related Transactions in our 2009 Proxy Statement and is incorporated herein by reference.

**Table of Contents****ITEM 14. Principal Accounting Fees and Services**

The information required by Item 14 will be set forth under the captions "Independent Registered Public Accounting Firm's Fees" and "Audit Committee Pre-Approval Policy" in our 2009 Proxy Statement and is incorporated herein by reference.

**PART IV****ITEM 15. Exhibits, Financial Statement Schedules**1. *Consolidated Financial Statements*

The Consolidated Financial Statements listed in the Index to Consolidated Financial Statements are filed as part of this Form.

2. *Financial Statement Schedules*

**MYLAN INC. AND SUBSIDIARIES**  
**SCHEDULE II VALUATION AND QUALIFYING ACCOUNTS**  
(in thousands)

Description	Beginning Balance	Additions (Deductions) Charged to Costs and Expenses	Additions (Deductions) Charged to Other Accounts	Deductions	Ending Balance
Allowance for doubtful accounts:					
Calendar year ended December 31, 2008	\$ 38,088	\$ (2,355)	\$ (2,502)	\$ (6,338)	\$ 26,893
Nine months ended December 31, 2007	\$ 15,149	\$ 9,959	\$ 13,255*	\$ (275)	\$ 38,088
Fiscal year ended March 31, 2007	\$ 10,954	\$ (500)	\$ 4,778**	\$ (83)	\$ 15,149
Valuation allowance for deferred tax assets:					
Calendar year ended December 31, 2008	\$ 76,100	\$ 53,421	\$ (16,285)	\$ (3,042)	\$ 110,194
Nine months ended December 31, 2007	\$ 18,355	\$ 33,545	\$ 24,200*	\$	\$ 76,100
Fiscal year ended March 31, 2007	\$ 1,644	\$ 5,531	\$ 11,180**	\$	\$ 18,355

\* Allowance recorded as part of the former Merck Generics business acquisition.

\*\* Allowance recorded as part of the Matrix acquisition.

3. *Exhibits*

3.1(a) Amended and Restated Articles of Incorporation of the registrant, filed as Exhibit 3.1 to the Form 10-Q for the quarterly period ended June 30, 2003, and incorporated herein by reference.

3.1(b)

Edgar Filing: MYLAN INC. - Form 10-K

- Amendment to Amended and Restated Articles of Incorporation of the registrant, filed as Exhibit 3.2 to the Report on Form 8-K filed with the SEC on October 5, 2007, and incorporated herein by reference.
- 3.1(c) Amendment to Amended and Restated Articles of Incorporation of the registrant, filed as Exhibit 3.1 to the Report on Form 8-K filed with the SEC on November 20, 2007, and incorporated herein by reference.
- 3.2 Bylaws of the registrant, as amended to date, filed as Exhibit 3.1 to the Report of Form 8-K filed on December 21, 2007, and incorporated herein by reference.
- 4.1(a) Rights Agreement dated as of August 22, 1996, between the registrant and American Stock Transfer & Trust Company, filed as Exhibit 4.1 to the Report on Form 8-K filed with the SEC on September 3, 1996, and incorporated herein by reference.

**Table of Contents**

- 4.1(b) Amendment to Rights Agreement dated as of November 8, 1999, between the registrant and American Stock Transfer & Trust Company, filed as Exhibit 1 to Form 8-A/A filed with the SEC on March 31, 2000, and incorporated herein by reference.
- 4.1(c) Amendment No. 2 to Rights Agreement dated as of August 13, 2004, between the registrant and American Stock Transfer & Trust Company, filed as Exhibit 4.1 to the Report on Form 8-K filed with the SEC on August 16, 2004, and incorporated herein by reference.
- 4.1(d) Amendment No. 3 to Rights Agreement dated as of September 8, 2004, between the registrant and American Stock Transfer & Trust Company, filed as Exhibit 4.1 to the Report on Form 8-K filed with the SEC on September 9, 2004, and incorporated herein by reference.
- 4.1(e) Amendment No. 4 to Rights Agreement dated as of December 2, 2004, between the registrant and American Stock Transfer & Trust Company, filed as Exhibit 4.1 to the Report on Form 8-K filed with the SEC on December 3, 2004, and incorporated herein by reference.
- 4.1(f) Amendment No. 5 to Rights Agreement dated as of December 19, 2005, between the registrant and American Stock Transfer & Trust Company, filed as Exhibit 4.1 to the Report on Form 8-K filed with the SEC on December 19, 2005, and incorporated herein by reference.
- 4.2(a) Indenture, dated as of July 21, 2005, between the registrant and The Bank of New York, as trustee, filed as Exhibit 4.1 to the Report on Form 8-K filed with the SEC on July 27, 2005, and incorporated herein by reference.
- 4.2(b) Second Supplemental Indenture, dated as of October 1, 2007, among the registrant, the Subsidiaries of the registrant listed on the signature page thereto and The Bank of New York, as trustee, filed as Exhibit 4.1 to the Report on Form 8-K filed with the SEC on October 5, 2007, and incorporated herein by reference.
- 4.3 Registration Rights Agreement, dated as of July 21, 2005, among the registrant, the Guarantors party thereto and Merrill Lynch, Pierce, Fenner & Smith Incorporated, BNY Capital Markets, Inc., KeyBanc Capital Markets (a Division of McDonald Investments Inc.), PNC Capital Markets, Inc. and SunTrust Capital Markets, Inc., filed as Exhibit 4.2 to the Report on Form 8-K filed with the SEC on July 27, 2005, and incorporated herein by reference.
- 4.4 Indenture, dated as of September 15, 2008, among the registrant, the guarantors named therein and Bank of New York Mellon as trustee, filed as Exhibit 4.1 to the Report on Form 8-K filed with the SEC on September 15, 2008, and incorporated herein by reference.
- 10.1 1986 Incentive Stock Option Plan, as amended to date, filed as Exhibit 10(b) to Form 10-K for the fiscal year ended March 31, 1993, and incorporated herein by reference.\*
- 10.2 1997 Incentive Stock Option Plan, as amended to date, filed as Exhibit 10.3 to Form 10-Q for the quarter ended September 30, 2002, and incorporated herein by reference.\*
- 10.3 1992 Nonemployee Director Stock Option Plan, as amended to date, filed as Exhibit 10(l) to Form 10-K for the fiscal year ended March 31, 1998, and incorporated herein by reference.\*
- 10.4(a) Amended and Restated 2003 Long-Term Incentive Plan, filed as Appendix A to Definitive Proxy Statement on Schedule 14A, filed with the SEC on March 28, 2008, and incorporated herein by reference.\*
- 10.4(b) Form of Stock Option Agreement under the 2003 Long-Term Incentive Plan, filed as Exhibit 10.4(b) to Form 10-K for the fiscal year ended March 31, 2005, and incorporated herein by reference.\*
- 10.4(c) Form of Restricted Share Award under the 2003 Long-Term Incentive Plan, filed as Exhibit 10.4(c) to Form 10-K for the fiscal year ended March 31, 2005, and incorporated herein by reference.\*
- 10.4(d) Amendment No. 1 to the Amended and Restated 2003 Long-Term Incentive Plan, dated as of December 17, 2008.\*
- 10.5 Mylan Inc. Severance Plan, amended as of December 17, 2008.\*
- 10.6 3.75% Cash Convertible Notes due 2015 Purchase Agreement dated September 9, 2008, among the registrant and the initial purchaser named therein, filed as Exhibit 1.1 to the Report on Form 8-K filed with the SEC on September 15, 2008, and incorporated herein by reference.

- 10.7(a) Confirmation of OTC Convertible Note Hedge Transaction dated September 9, 2008, among the registrant, Merrill Lynch International and Merrill Lynch, Pierce, Fenner & Smith Incorporated, filed as Exhibit 10.1 to the Report on Form 8-K filed with the SEC on September 15, 2008, and incorporated herein by reference.

**Table of Contents**

- 10.7(b) Confirmation of OTC Convertible Note Hedge Transaction, amended as of November 25, 2008, among the registrant, Merrill Lynch International and Merrill Lynch, Pierce, Fenner & Smith Incorporated.
- 10.8 Confirmation of OTC Convertible Note Hedge Transaction dated September 9, 2008, between the registrant and Wells Fargo Bank, National Association, filed as Exhibit 10.2 to the Report on Form 8-K filed with the SEC on September 15, 2008, and incorporated herein by reference.
- 10.9 Confirmation of OTC Warrant Transaction dated September 9, 2008, among the registrant, Merrill Lynch International and Merrill Lynch, Pierce, Fenner & Smith Incorporated, filed as Exhibit 10.3 to the Report on Form 8-K filed with the SEC on September 15, 2008, and incorporated herein by reference.
- 10.10 Confirmation of OTC Warrant Transaction dated September 9, 2008, between the registrant and Wells Fargo Bank, National Association, filed as Exhibit 10.4 to the Report on Form 8-K filed with the SEC on September 15, 2008, and incorporated herein by reference.
- 10.11 Amendment to Confirmation of OTC Warrant Transaction dated September 15, 2008 among the registrant, Merrill Lynch International and Merrill Lynch, Pierce, Fenner & Smith Incorporated, filed as Exhibit 10.5 to the Report on Form 8-K filed with the SEC on September 15, 2008, and incorporated herein by reference.
- 10.12 Amendment to Confirmation of OTC Warrant Transaction dated September 15, 2008, between the registrant and Wells Fargo Bank, National Association, filed as Exhibit 10.6 to the Report on Form 8-K filed with the SEC on September 15, 2008, and incorporated herein by reference.
- 10.13 Amendment to Confirmation of OTC Warrant Transaction dated as of September 9, 2008 among Mylan Inc., Merrill Lynch International and Merrill Lynch, Pierce, Fenner & Smith Incorporated, filed as Exhibit 10.7 to the Report on Form 8-K filed with the SEC on September 15, 2008, and incorporated herein by reference.
- 10.14 Amendment to Confirmation of OTC Warrant Transaction dated as of September 9, 2008 among Mylan Inc., Merrill Lynch International and Merrill Lynch, Pierce, Fenner & Smith Incorporated, filed as Exhibit 10.8 to the Report on Form 8-K filed with the SEC on September 15, 2008, and incorporated herein by reference.
- 10.15 Calculation Agent Agreement dated September 9, 2008, among the registrant, Wells Fargo Bank, National Association and Goldman Sachs International, filed as Exhibit 10.9 to the Report on Form 8-K filed with the SEC on September 15, 2008, and incorporated herein by reference.
- 10.16(a) Amended and Restated Executive Employment Agreement dated as of April 3, 2006, between the registrant and Robert J. Coury filed as Exhibit 10.5 to Form 10-K for the fiscal year ended March 31, 2006, and incorporated herein by reference.\*
- 10.16(b) Amendment No. 1 to Amended and Restated Executive Employment Agreement, dated as of December 22, 2008, between the registrant and Robert J. Coury.\*
- 10.17(a) Executive Employment Agreement dated as of July 1, 2004, between the registrant and Edward J. Borkowski, filed as Exhibit 10.27 to Form 10-Q/A for the quarter ended September 30, 2004, and incorporated herein by reference.\*
- 10.17(b) Amendment No. 1 to Executive Employment Agreement dated as of April 3, 2006, between the registrant and Edward J. Borkowski filed as Exhibit 10.6(b) to Form 10-K for the fiscal year ended March 31, 2006, and incorporated herein by reference.\*
- 10.17(c) Amendment No. 2 to Executive Employment Agreement dated as of March 12, 2008, by and between registrant and Edward J. Borkowski filed as Exhibit 99.1 to the Report on Form 8-K filed with the SEC on March 12, 2008, and incorporated herein by reference.\*
- 10.17(d) Amendment No. 3 to Executive Employment Agreement dated as of December 22, 2008, by and between registrant and Edward J. Borkowski.\*
- 10.18(a) Executive Employment Agreement, dated as of January 31, 2007, between the registrant and Heather Bresch filed as Exhibit 10.3 to Form 10-Q for the quarter ended March 31, 2008, and incorporated herein by reference.\*

- 10.18(b) Amendment No. 1 to Executive Employment Agreement dated as of October 2, 2007, by and between the registrant and Heather Bresch filed as Exhibit 10.4 to Form 10-Q for the quarter ended March 31, 2008, and incorporated herein by reference.\*
- 10.18(c) Amendment No. 2 to Executive Employment Agreement dated as of December 22, 2008, by and between the registrant and Heather Bresch.\*



**Table of Contents**

- 10.19(a) Executive Employment Agreement, dated as of January 31, 2007, between the registrant and Rajiv Malik filed as Exhibit 10.6 to Form 10-Q for the quarter ended March 31, 2008, and incorporated herein by reference.\*
- 10.19(b) Amendment No. 1 to Executive Employment Agreement dated as of October 2, 2007, by and between the registrant and Rajiv Malik filed as Exhibit 10.7 to Form 10-Q for the quarter ended March 31, 2008, and incorporated herein by reference.\*
- 10.19(c) Amendment No. 2 to Executive Employment Agreement dated as of December 22, 2008, by and between the registrant and Rajiv Malik.\*
- 10.20(a) Retirement Benefit Agreement dated as of December 31, 2004, between the registrant and Robert J. Coury filed as Exhibit 10.7 to Form 10-Q for the quarter ended December 31, 2004, and incorporated herein by reference.\*
- 10.20(b) Amendment No. 1 to Retirement Benefit Agreement dated as of April 3, 2006, between the registrant and Robert J. Coury filed as Exhibit 10.11(b) to Form 10-K for the fiscal year ended March 31, 2006, and incorporated herein by reference.\*
- 10.20(c) Amendment No. 2 to Retirement Benefit Agreement dated as of December 22, 2008, between the registrant and Robert J. Coury.\*
- 10.21(a) Retirement Benefit Agreement dated as of December 31, 2004, between the registrant and Edward J. Borkowski, filed as Exhibit 10.8 to Form 10-Q for the quarter ended December 31, 2004, and incorporated herein by reference.\*
- 10.21(b) Amendment No. 1 to Retirement Benefit Agreement dated as of April 3, 2006, between the registrant and Edward J. Borkowski filed as Exhibit 10.12(b) to Form 10-K for the fiscal year ended March 31, 2006, and incorporated herein by reference.\*
- 10.21(c) Amendment No. 2 to Retirement Benefit Agreement dated as of December 22, 2008, between the registrant and Edward J. Borkowski.\*
- 10.22 Retirement Benefit Agreement dated January 27, 1995, between the registrant and C.B. Todd, filed as Exhibit 10(b) to Form 10-K for the fiscal year ended March 31, 1995, and incorporated herein by reference.\*
- 10.23(a) Retirement Benefit Agreement dated January 27, 1995, between the registrant and Milan Puskar, filed as Exhibit 10(b) to Form 10-K for the fiscal year ended March 31, 1995, and incorporated herein by reference.\*
- 10.23(b) First Amendment to Retirement Benefit Agreement dated September 27, 2001, between the registrant and Milan Puskar, filed as Exhibit 10.1 to Form 10-Q for the quarter ended September 30, 2001, and incorporated herein by reference.\*
- 10.23(c) Amendment No. 2 to Retirement Benefit Agreement dated as of April 25, 2008, by and between registrant and Milan Puskar, filed as Exhibit 10.1 to Form 10-Q for the quarter ended June 30, 2008, and incorporated herein by reference.\*
- 10.24 Split Dollar Life Insurance Arrangement between the registrant and the Milan Puskar Irrevocable Trust filed as Exhibit 10(h) to Form 10-K for the fiscal year ended March 31, 1996, and incorporated herein by reference.\*
- 10.25(a) Transition and Succession Agreement dated as of December 15, 2003, between the registrant and Robert J. Coury, filed as Exhibit 10.19 to Form 10-Q for the quarter ended December 31, 2003, and incorporated herein by reference.\*
- 10.25(b) Amendment No. 1 to Transition and Succession Agreement dated as of December 2, 2004, between the registrant and Robert J. Coury, filed as Exhibit 10.1 to Form 10-Q for the quarter ended December 31, 2004, and incorporated herein by reference.\*
- 10.25(c) Amendment No. 2 to Transition and Succession Agreement dated as of April 3, 2006, between the registrant and Robert J. Coury filed as Exhibit 10.19(c) to Form 10-K for the fiscal year ended March 31, 2006, and incorporated herein by reference.\*

Edgar Filing: MYLAN INC. - Form 10-K

- 10.25(d) Amendment No. 3 to Transition and Succession Agreement dated as of December 22, 2008, between the registrant and Robert J. Coury.\*
- 10.26(a) Transition and Succession Agreement dated as of December 15, 2003, between the registrant and Edward J. Borkowski, filed as Exhibit 10.20 to Form 10-Q for the quarter ended December 31, 2003, and incorporated herein by reference.\*

**Table of Contents**

10.26(b)	Amendment No. 1 to Transition and Succession Agreement dated as of December 2, 2004, between the registrant and Edward J. Borkowski, filed as Exhibit 10.2 to Form 10-Q for the quarter ended December 31, 2004, and incorporated herein by reference.*
10.26(c)	Amendment No. 2 to Transition and Succession Agreement dated as of April 3, 2006, between the registrant and Edward J. Borkowski filed as Exhibit 10.20(c) to Form 10-K for the fiscal year ended March 31, 2006, and incorporated herein by reference.*
10.26(d)	Amendment No. 3 to Transition and Succession Agreement dated as of December 22, 2008, between the registrant and Edward J. Borkowski.*
10.27(a)	Amended and Restated Transition and Succession Agreement dated as of October 2, 2007, between the registrant and Heather Bresch, filed as Exhibit 10.2 to Form 10-Q for the quarter ended March 31, 2008, and incorporated herein by reference.*
10.27(b)	Amendment No. 1 to Transition and Succession Agreement dated as of December 22, 2008, between the registrant and Heather Bresch.*
10.28(a)	Transition and Succession Agreement dated as of January 31, 2007, between the registrant and Rajiv Malik, filed as Exhibit 10.5 to Form 10-Q for the quarter ended March 31, 2008, and incorporated herein by reference.*
10.28(b)	Amendment No. 1 to Transition and Succession Agreement dated as of December 22, 2008, between the registrant and Rajiv Malik.*
10.29	Executives Retirement Savings Plan, filed as Exhibit 10.14 to Form 10-K for the fiscal year ended March 31, 2001, and incorporated herein by reference.*
10.30	Supplemental Health Insurance Program For Certain Officers of the registrant, effective December 15, 2001, filed as Exhibit 10.1 to Form 10-Q for the quarter ended December 31, 2001, and incorporated herein by reference.*
10.31	Form of Indemnification Agreement between the registrant and each Director, filed as Exhibit 10.31 to Form 10-Q/A for the quarter ended September 30, 2004, and incorporated herein by reference.*
10.32	Description of the registrant's Director Compensation Arrangements in effect as of the date hereof.*
10.33	Agreement Regarding Consulting Services and Shareholders Agreement dated as of December 31, 2007 by and among the registrant, MP Laboratories (Mauritius) Ltd, Prasad Nimmagadda, Globex and G2 Corporate Services Limited, filed as Exhibit 10.26 to Form 10-KT/A for the period ended December 31, 2007, and incorporated herein by reference.
10.34(a)	Share Purchase Agreement dated May 12, 2007 by and among Merck Generics Holding GmbH, Merck Internationale Beteiligung GmbH, Merck KGaA and the registrant, filed with the Report on Form 8-K filed with the SEC on May 17, 2007, and incorporated herein by reference.
10.34(b)	Amendment No. 1 to Share Purchase Agreement by and among the registrant and Merck Generics Holding GmbH, Merck S.A. Merck Internationale Beteiligung GmbH and Merck KGaA, filed as Exhibit 10.1 to the Report on Form 8-K filed with the SEC on October 5, 2007, and incorporated herein by reference.
10.35	Amended and Restated Credit Agreement dated as of December 20, 2007 by and among the registrant, Mylan Luxembourg 5 S.à.r.l., certain lenders and JPMorgan Chase Bank, National Association, as Administrative Agent, filed as Exhibit 10.1 to the Report on Form 8-K filed with the SEC on December 27, 2007, and incorporated herein by reference.
10.36	Separation Agreement and Release dated February 20, 2009, by and between the registrant and Edward J. Borkowski.*
21	Subsidiaries of the registrant.
23	Consent of Independent Registered Public Accounting Firm.
31.1	Certification of CEO pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of CFO pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32	Certification of CEO and CFO pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

\* Denotes management contract or compensatory plan or arrangement.

129

---

**Table of Contents**

**SIGNATURES**

Pursuant to the requirements of section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this Form to be signed on its behalf by the undersigned, thereunto duly authorized on February 23, 2009.

Mylan Inc.

by /s/ ROBERT J. COURY

Robert J. Coury  
Vice Chairman and  
Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this Form has been signed below by the following persons on behalf of the registrant and in the capacities indicated as of February 23, 2009.

**Signature**

**Title**

/s/ ROBERT J. COURY

Vice Chairman, Chief Executive Officer and Director (*Principal Executive Officer*)

Robert J. Coury

/s/ EDWARD J. BORKOWSKI

Executive Vice President and Chief Financial Officer  
(*Principal Financial Officer*)

Edward J. Borkowski

/s/ DANIEL C. RIZZO, JR.

Senior Vice President and Corporate Controller  
(*Principal Accounting Officer*)

Daniel C. Rizzo, Jr.

/s/ MILAN PUSKAR

Chairman and Director

Milan Puskar

/s/ WENDY CAMERON

Director

Wendy Cameron

/s/ NEIL DIMICK

Director

Neil Dimick

/s/ DOUGLAS J. LEECH

Director

Douglas J. Leech

/s/ JOSEPH C. MAROON, M.D. Director

Joseph C. Maroon, M.D.

/s/ PRASAD NIMMAGADDA Director

Prasad Nimmagadda

/s/ ROD PIATT Director

Rod Piatt

/s/ C.B. TODD Director

C.B. Todd

/s/ R.L. VANDERVEEN, PH.D., R.PH. Director

R.L. Vanderveen, Ph.D., R.Ph.

**Table of Contents**

**EXHIBIT INDEX**

10.4(d)	Amendment No. 1 to the Mylan Inc. Amended and Restated 2003 Long-Term Incentive Plan, dated as of December 17, 2008.
10.5	Mylan Inc. Severance Plan as of December 17, 2008.
10.7(b)	Confirmation of the Amendment to the OTC Convertible Note Hedge Transaction dated as of November 25, 2008, among the registrant, Merrill Lynch International and Merrill Lynch, Pierce, Fenner & Smith Incorporated.
10.16(b)	Amendment to Amended and Restated Executive Employment Agreement, dated as of December 22, 2008, between the registrant and Robert J. Coury.
10.17(d)	Amendment No. 3 to Executive Employment Agreement dated as of December 22, 2008, by and between registrant and Edward J. Borkowski.
10.18(c)	Amendment No. 2 to Executive Employment Agreement dated as of December 22, 2008, by and between the registrant and Heather Bresch.
10.19(c)	Amendment No. 2 to Executive Employment Agreement dated as of December 22, 2008, by and between the registrant and Rajiv Malik.
10.20(c)	Amendment No. 2 to Retirement Benefit Agreement dated as of December 22, 2008, between the registrant and Robert J. Coury.
10.21(c)	Amendment No. 1 to Retirement Benefit Agreement dated as of December 22, 2008, between the registrant and Edward J. Borkowski.
10.25(d)	Amendment No. 3 to Transition and Succession Agreement dated as of December 22, 2008, between the registrant and Robert J. Coury.
10.26(d)	Amendment No. 3 to Transition and Succession Agreement dated as of December 22, 2008, between the registrant and Edward J. Borkowski.
10.27(b)	Amendment No. 1 to Transition and Succession Agreement dated as of December 22, 2008, between the registrant and Heather Bresch.
10.28(b)	Amendment No. 1 to Transition and Succession Agreement dated as of December 22, 2008, between the registrant and Rajiv Malik.
10.32	Description of the registrant's Director Compensation Arrangements in effect as of the date hereof.*
10.36	Separation Agreement and Release dated February 20, 2009, by and between the registrant and Edward J. Borkowski.*
21	Subsidiaries of the registrant.
23	Consent of Independent Registered Public Accounting Firm.
31.1	Certification of CEO pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of CFO pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32	Certification of CEO and CFO pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.