

MYLAN INC.  
Form 10-KT/A  
March 07, 2008

**Table of Contents**

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

**FORM 10-K/A**

- o Annual Report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934  
For the Fiscal Year Ended**
- þ Transition Report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934  
For the transition period from April 1, 2007 to December 31, 2007**

**Commission File No. 1-9114**

**MYLAN INC.**

(Exact name of registrant as specified in its charter)

**Pennsylvania**  
(State of Incorporation)

**25-1211621**  
(IRS Employer Identification No.)

**1500 Corporate Drive, Canonsburg, Pennsylvania 15317  
(724) 514-1800**

(Address, including zip code, and telephone number, including area code, of principal executive offices)

**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	New York Stock Exchange
6.50% Mandatory Convertible Preferred Stock	New York Stock Exchange

**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-KT/A

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 September 28, 2007, the last business day of the registrant's most recently completed second fiscal quarter (September 30, 2007) was approximately \$3,860,810,954.

The number of outstanding shares of common stock of the registrant as of February 26, 2008, was 304,372,325.

**DOCUMENTS INCORPORATED BY REFERENCE**

<b>Document</b>	<b>Parts of Form 10-K into which Document is Incorporated</b>
Proxy Statement for the 2008 Annual Meeting of Shareholders, which will be filed with the Securities and Exchange Commission within 120 days after the end of the registrant's period ended December 31, 2007.	III

---

**Table of Contents**

**Explanatory Note:**

This Amendment No. 1 on Form 10-K/A (the Form 10-K/A ) amends our transition report for the period ended December 31, 2007, originally filed with the Securities and Exchange Commission on February 29, 2008 (the Form 10-K ). We are filing this Form 10-K/A to correct typographical errors.

Specifically, (1) the dates between the double asterisks (\*\*), in (1) below, were inadvertently noted as 2007 in ITEM 7, Management s Discussion and Analysis under the heading Strategic Initiatives and in ITEM 8, Financial Statements and Supplementary Data , Note 18, Subsequent Events , and both such sections are hereby amended to reflect the correct date, as shown below. (2) Also, within ITEM 7, under the heading Liquidity and Capital Resources , the number between the double asterisks (\*\*), in (2) below, referred to as cash flows from operating activities was incorrectly shown as \$172.7 million and such section is also amended to reflect the correct amount, as shown below. (3) In ITEM 9A, Controls and Procedures , the page references for Management s Report on Internal Control over Financial Reporting between double asterisks (\*\*), in (3) below, was incorrectly shown as page 93 and the page reference for our independent registered public accounting firm s report on Internal Control over Financial Reporting between double asterisks (\*\*) was incorrectly shown as page 95. This section is hereby amended to include the correct page references, as shown below.

- (1) On February 27, \*\*2008\*\*, Mylan executed an agreement with Forest Laboratories, whereby Mylan sold its rights to Nebivolol, an FDA approved product for the treatment of hypertension which is marketed by Forest under the Brand name Bystolic™. Mylan will receive a one-time cash payment of \$370.0 million (within ten business days from the execution of the agreement) and will retain its contractual royalties for three years, through calendar 2010.
- (2) Cash flows from operating activities were \*\*\$167.7\*\* million for the transition period, consisting primarily of non-cash add-backs for acquired in-process research and development and depreciation and amortization, partially offset by a net decrease in operating assets and liabilities.
- (3) During the quarter ended December 31, 2007, the Company completed its acquisition of Merck Generics, discussed in Management s Report on Internal Control over Financial Reporting on page \*\*106\*\*, and implemented a new consolidation system to enhance the Company s worldwide consolidation function.

Management s Report on Internal Control over Financial Reporting is on page \*\*106\*\*. The effectiveness of the Company s internal control over financial reporting as of December 31, 2007, has been audited by Deloitte & Touche LLP, an independent registered public accounting firm, as stated in their report which is on pages \*\*108-109\*\*.

As required by Rule 12b-15 under the Securities Exchange Act of 1934, new certifications of our principal executive officer and principal financial officer are being filed as exhibits to this 10-K/A.

No other information contained in the original filing is amended by this 10-K/A. The 10-K has been corrected and furnished in its entirety in this 10-K/A. Except as described above, this amendment does not change any previously reported financial results, modify or update disclosures in the original filing or reflect events occurring after the date of the original filing.

---

MYLAN INC.

INDEX TO FORM 10-K  
For the Nine Months Ended December 31, 2007

	<b>Page</b>
<b>PART I</b>	
ITEM 1. Business	3
ITEM 1A. Risk Factors	20
ITEM 1B. Unresolved Staff Comments	37
ITEM 2. Properties	37
ITEM 3. Legal Proceedings	39
ITEM 4. Submission of Matters to a Vote of Security Holders	41
<b>PART II</b>	
ITEM 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities	42
ITEM 6. Selected Financial Data	44
ITEM 7. Management's Discussion and Analysis of Results of Operations and Financial Condition	45
ITEM 7A. Quantitative and Qualitative Disclosures about Market Risk	63
ITEM 8. Financial Statements and Supplementary Data	65
ITEM 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure	110
ITEM 9A. Controls and Procedures	110
ITEM 9B. Other Information	111
<b>PART III</b>	
ITEM 10. Directors, Executive Officers and Corporate Governance	111
ITEM 11. Executive Compensation	111
ITEM 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	111
ITEM 13. Certain Relationships and Related Transactions, and Director Independence	111
ITEM 14. Principal Accounting Fees and Services	111
<b>PART IV</b>	
ITEM 15. Exhibits and Financial Statement Schedules	112
Signatures	116
<u>EX-10.26</u>	
<u>EX-21</u>	
<u>EX-23</u>	
<u>EX-31.1</u>	
<u>EX-31.2</u>	
<u>EX-32</u>	

**Table of Contents**

**PART I**

**ITEM 1. Business**

Mylan Inc. and its subsidiaries (the Company, Mylan, 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 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. As a result, this Form 10-K is a transition report and includes financial information for the period from April 1, 2007 through December 31, 2007 (the Transition Period). Subsequent to this report, our reports on Form 10-K will cover the calendar year January 1st to December 31st. We refer to the period beginning April 1, 2006 through March 31, 2007 as fiscal 2007 and the period beginning April 1, 2005 through March 31, 2006 as fiscal 2006.

**Overview**

We have attained a position of leadership in the United States (U.S.) generic pharmaceutical industry through our ability to obtain Abbreviated New Drug Application (ANDA) approvals, our uncompromising quality control and our devotion to customer service. With the additions of Matrix and Merck Generics, 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 for the future. We expect that as a result of these acquisitions we will be less dependent on any single market or product and will be able to compete on a global basis.

Through Matrix Laboratories Limited (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 second largest API manufacturer with respect to the number of drug master files (DMFs) filed with regulatory agencies, with more than 165 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.

On October 2, 2007, Mylan completed its acquisition of the generic pharmaceutical business of Merck KGaA (Merck Generics) to become one of the largest quality generics and specialty pharmaceutical companies in the world. With this acquisition, Mylan became the third largest generic company worldwide with a global presence in more than 90 countries. Mylan's broad product offering now includes more than 570 products in a wide range of therapeutic areas. In addition to solid, oral dosage pharmaceuticals, 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. Mylan has a global pipeline with more than 255 applications or dossiers pending regulatory approval. Mylan will benefit from substantial operational efficiencies and economies of scale from increased sales volumes and its vertically and horizontally integrated platform.

With the addition of Merck Generics, Mylan will now report as three reportable segments, the Generics Segment, the Matrix Segment and the Specialty Segment. Mylan previously reported as two segments, the Mylan Segment (which is now included in the Generics Segment) and the Matrix Segment. In accordance with Statement of Financial Accounting Standards (SFAS) No. 131, *Disclosures about Segments of an Enterprise and Related Information*,

information for earlier periods has been recast. Refer to Note 15 in the Company's Consolidated Financial Statements included elsewhere in this Form 10-K for financial and geographical information related to these 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, Middle East, and Africa (collectively, EMEA), and Australia, Japan and New Zealand (collectively, Asia Pacific). Our specialty pharmaceutical business is conducted by Dey (Dey), headquartered in Napa, California. Our API business is conducted principally through our majority-owned subsidiary, Matrix, which is headquartered in Hyderabad, India and includes its subsidiary, Docpharma, which is primarily a distributor of pharmaceutical products in the Benelux region of Europe.

Mylan believes that the breadth and depth of its generics business provide it with 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 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 they are sold with little or no competition. 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 (Waxman-Hatch 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 ever-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 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 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 re-packages and markets products either obtained from MPI or purchased from third parties, in unit dose formats, for use primarily in hospitals and other medical institutions.

In the U.S., we have one of the largest product portfolios among all generic pharmaceutical companies, consisting of approximately 180 products, of which approximately 171 are in capsule or tablet form in an aggregate of approximately 457 dosage strengths. Included in these totals are 16 extended release products in a total of 41 dosage strengths.

In addition to those products that we manufacture in the U.S., we also market, principally through UDL, 74 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 allows us to successfully meet our customers' needs and helps us to better compete in the generic industry over the long term.

Our U.S. product portfolio also includes 3 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, carbidopa and levodopa, buspirone and levothyroxine sodium. 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. This can result in up to 180 days of generic exclusivity.

Through Genpharm Inc. ( Genpharm ), our wholly-owned Canadian subsidiary acquired as part of the Merck Generics acquisition, we manufacture and market generic pharmaceuticals in Canada. Genpharm is the fourth 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 Merck Generics. We have operations in 17 countries in EMEA. Of the top five generic pharmaceutical markets in Europe, we hold a top three market share position in four, consisting of France, the United Kingdom ( UK ), Spain and Italy.

**Table of Contents**

In France, we market our products through our subsidiary, Merck Generiques, using a sales force of approximately 160 representatives. The French generics market is primarily a branded generics market, with pharmacists serving as the key decision makers. France has the third largest generic market in Europe with sales of \$3.0 billion in 2007, and we hold the number one market share position, with over 300 products in the market.

In the UK, our subsidiary, Generics (UK) Limited, offers a broad product portfolio of over 300 pharmaceutical products. The British generics market is a highly competitive traditional generics substitution market, with the wholesalers and pharmacies serving as the key decision makers. The reimbursement market had sales of approximately \$4.7 billion, but prices at the wholesale dealing level are significantly lower, making the UK the third largest market in Europe. As of July 2007, Generics (UK) Limited held an estimated market share of approximately 14%, at wholesaler dealing level ranking it as the number two company in the reimbursement market. Generics (UK) Limited is well positioned as a preferred supplier to wholesalers and is also focused on areas such as multiple independent retail pharmacies.

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 maker and more recently, with health insurance companies starting to play a major role. The German generics market had sales of approximately \$14.0 billion in 2006 and is the largest generic market in Europe. As of August 2006, 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.

In Spain, where we market our products through our subsidiary Merck Genericos, we are the number three ranked company in terms of generic pharmaceutical market share. The Spanish generics market is a branded generics market, with the physician and/or the pharmacist as the key decision maker 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 market in Spain had sales of approximately \$1.2 billion in 2006, making it the fourth largest generic market in Europe. The generic market made up approximately 5.9% in 2006 of the total Spanish pharmaceutical market by sales 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 generics market with a focus on brand quality and the importance of being first-to-market in order to capture and maintain market share. The generics market in Italy had sales of approximately \$400.0 million in 2006. We believe the Italian generic market is underpenetrated, with generics representing only 1.3% 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.

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 key to our future growth and success in EMEA.

In connection with Mylan's acquisition of Merck Generics, Mylan had the option to acquire several new and emerging Merck Generics businesses within Central and Eastern Europe (CEE). The main markets for Mylan in CEE will be Poland, Slovakia, Slovenia, Hungary, and the Czech Republic. The Company has exercised its option to acquire these businesses.

In conjunction with the Merck Generics acquisition, the Company entered into a transitional services agreement with Merck KGaA that provides for certain general and administrative support in certain countries through October 2, 2008. The Company is currently implementing a plan and incurring costs to replace these services and is moving toward the consummation of the transfer of the businesses.

## **Table of Contents**

### *Asia Pacific*

Similar to EMEA, generic pharmaceutical sales in Asia Pacific are derived principally through wholly-owned subsidiaries acquired through the acquisition of Merck Generics. We hold the number one market position 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 volume as of August 2007, 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 \$800.0 million in 2006 and made up approximately 9.0% of the total Australian pharmaceutical market by volume. 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., our wholly-owned subsidiary and the largest generics company in New Zealand.

Mylan Seiyaku, our Japanese subsidiary, offers a broad portfolio of over 400 products with a focus on antibiotics, anti-diabetics, oncology and skin and allergy medications. We have a manufacturing and R&D 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 \$3.3 billion in 2006. The generic market made up approximately 5% of the total Japanese pharmaceutical market by sales. Recent pro-generics government actions include: higher patient co-pays, fixed hospital reimbursement for certain procedures, and pharmacy substitution. 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%, 14% and 17% of our Generics Segment net revenues for the nine months ended December 31, 2007 and fiscal years 2007 and 2006, respectively, were contributed by calcium channel blockers, primarily nifedipine and amlodipine. Additionally, approximately 29%, 19%, and 15% of our Generics Segment net revenues during the nine months ended December 31, 2007 and fiscal years 2007 and 2006 were contributed by 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 have historically been derived primarily through the sale of two products, EpiPen and DuoNeb.

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 market share of over 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.

DuoNeb is a nebulized unit dose formulation of ipratropium bromide and albuterol sulfate for treatment of chronic obstructive pulmonary disorder ( COPD ). DuoNeb, which was developed and patented by Dey, lost exclusivity in July 2007, at which time generic competition entered the market. As a result we expect sales of DuoNeb to decline.

Perforomist™, 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 COPD patients, including those with chronic bronchitis and emphysema.

Zyflo CR™, zileuton extended-release tablet, was launched on September 27, 2007. Sold through a co-promotion with Critical Therapeutics, Zyflo CR is a leukotriene synthesis inhibitor indicated for the prophylaxis

## **Table of Contents**

and chronic treatment of asthma in adults and children 12 years of age or older. Zylflo CR competes in the approximately \$7.9 billion U.S. asthma market. Zylflo CR provides an alternative therapy for sub-optimally controlled asthma patients.

Cyanokit<sup>tm</sup>, which was launched in March 2007, is indicated for the treatment of smoke inhalation or cyanide poisoning. Cyanokit has been used safely in Europe for over 10 years.

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 71% and 27% of our Specialty Segment net revenues for the nine month period ended December 31, 2007 were contributed by respiratory agents and central nervous system agents, respectively.

### *Matrix Segment*

We conduct our API business through Matrix, in which we own a 71.5% interest. Matrix is the world's second largest API manufacturer with respect to the number of DMFs filed with regulatory agencies. Matrix currently has more than 165 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 APIs, used in the treatment of HIV. Matrix is a leading supplier of generic anti-retroviral APIs.

Matrix has 10 API and intermediate manufacturing facilities and one finished dosage form ( FDF ) facility. Of these, seven, including the FDF facility, are FDA approved, making Matrix one of the largest companies in India in terms of FDA-approved API manufacturing capacity. In addition, Matrix has manufacturing facilities in China and holds investments in companies located elsewhere in India, South Africa and Europe.

Our future success in API is dependent upon continuing to leverage our research and development capabilities to produce low-cost, high-quality API, while capitalizing on the greater API volumes afforded through our horizontally and vertically integrated platform.

Approximately 23%, 15%, 13%, and 13% of our Matrix Segment net revenues for the nine-month period ended December 31, 2007 were contributed by anti-infective agents, central nervous system agents, gastrointestinal agents, and cardiovascular agents, respectively.

## **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 Merck Generics 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;

development of drugs that are technically difficult to formulate or manufacture either because of unusual factors that affect their stability or bioequivalence or unusually stringent regulatory requirements;

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

## **Table of Contents**

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;

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 nine months ended December 31, 2007, we received 32 application approvals from the FDA, consisting of 16 final ANDA approvals, 14 tentative ANDA approvals, one supplemental ANDA approval and one tentative supplemental ANDA approval.

We have a robust generic product pipeline. As of December 31, 2007, including Matrix, we had 88 product applications pending at the FDA, representing approximately \$154.4 billion in U.S. sales for the 12 months ended June 30, 2007 for the brand name versions of these products, according to IMS Health data. Fifteen 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.

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 three years. Between 2007 and 2009, approximately \$45 billion is expected in U.S. brand sales for such products. 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, Medicare and other reimbursement legislation or programs govern reimbursement levels and require all pharmaceutical manufacturers to rebate a percentage of their revenues arising from Medicare and/or Medicaid-reimbursed drug sales to individual states. The required rebate is currently 11% of the average manufacturer's price for sales of Medicaid-reimbursed products marketed under ANDAs. Sales of Medicare and/or Medicaid-reimbursed products marketed under NDAs generally 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 an NOC for that product for the uses specified in the ANDS, subject to any court order that may be made in the second track of the approval process.

The 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 (Notice of Compliance) Regulations. The owner or exclusive licensee, or Originator, of patents relating to the brand drug for which it has an NOC may have established a list of patents administered by Health Canada enumerating all the patents claiming the medicinal ingredient, formulation, dosage form or the use of the medicinal ingredient. It is possible that even though the patent for the API may have expired, the Originator may have other patents on the list which relate to new forms of the API,

a formulation or additional uses. Most brand name drugs have an associated patent list containing one or more unexpired patents claiming the medicinal ingredient itself or a use of the medicinal ingredient (a claim for the use of the medicinal ingredient for the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state or its symptoms). In its ANDS, a generic applicant must make at least one of the statutory allegations with respect to each patent on the patent list, for example, alleging that the patent is invalid or would not be infringed and explaining the basis for that allegation. In conjunction with filing its ANDS, the generic applicant

## **Table of Contents**

is required to serve a Notice of Allegation ( NOA ) on the Originator which gives a detailed statement of the factual and legal basis for its allegations in the ANDS. The Originator may commence a court application within 45 days after it has been served with the NOA if it takes the position that the allegations are not justified. When the application is filed in court and served on Health Canada, Health Canada may not issue an NOC until the earlier of the determination of the application by the court after a hearing or the expiration of 24 months from the commencement of the application. The period may be shortened or lengthened by the court in certain circumstances. An NOC can be obtained for a generic product only if the applicant is successful in defending the application under the Patented Medicines (Notice of Compliance) Regulations in court. The legal costs incurred in connection with the application could be substantial.

Section C.08.004.1 of the Food and Drug Regulations is the so-called data protection provision and the current version of this section applies in respect of all drugs for which an NOC was issued on or after June 17, 2006. A subsequent applicant for approval to market a drug for which an NOC has already been issued does not need to perform duplicate clinical trials similar to those conducted by the first NOC holder, but is permitted to demonstrate safety and efficacy by submitting data demonstrating that its formulation is bioequivalent to the formulation that was issued for the first NOC. The first party to obtain an NOC for a drug will have an eight-year period of exclusivity starting from the date it received its NOC based on those clinical data. A subsequent applicant for approval who seeks to establish safety and efficacy by comparing its product to the product that received the first NOC will not be able to file its own application until six years following the issuance of the first NOC have expired. The Minister of Health will not be permitted to issue an NOC to that applicant until eight years following the issuance of the first NOC have expired this additional two-year period will correspond in most cases to the 24-month automatic stay under the Regulations. If the first person provides the Minister with the description and results of clinical trials relating to the use of the drug in pediatric populations, it will be entitled to an extra six months of data protection. A drug is only entitled to data protection so long as it is being marketed in Canada.

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 cGMP, 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 an 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 cGMP. 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 cGMP compliance.

*EMEA*

The European Union provides 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 and 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 procedure, whereby after submission and approval by the authorities of the so called reference member state, further applications can be submitted into the other chosen member states (known as concerned member states). Theoretically, the authorization of the reference member state should be mutually recognized by the concerned member states. More typically, however, a degree of

**Table of Contents**

re-evaluation is carried out by the concerned member states. In November 2005, this legislation was further optimized. In addition to the mutual recognition procedure, the new decentralized procedure was introduced. This second procedure is also led by the reference member state but applications are simultaneously submitted to all selected countries. From 2005, the Centralized Procedure operated by the European Medicines Agency 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 mutual recognition ( MR ) procedure, a marketing authorization is first sought in one member state from the national regulatory agency (the Reference Member State ( RMS )). The RMS makes its assessment report on the quality, efficacy and safety of the medicinal product available to other Concerned Member States ( CMSs ) where marketing authorizations are also sought under the MR procedure. The MR procedure is not automatic: while one CMS may refuse recognition of the marketing authorization granted by the RMS based on grounds of potential serious risk to public health, other CMS may grant their approval and authorization regardless of an outgoing procedure to ascertain a potential serious risk of the public health.

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. The aim of the decentralized procedure is to avoid the problem of member states objecting to the initial marketing authorization. However, if there are any problems they will be dealt with by the CMD (the coordination group for MR and decentralized procedures) under a 60-day 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 a considerable reduction in the future administrative burden on the pharmaceutical company with regard to variations, extensions, renewals, etc. concerning its national marketing authorizations.

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 mutual recognition 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 centralized 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 bio equivalent 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

## **Table of Contents**

pharmaceutical product to be authorized. The generic applicant can file an abridged application for marketing authorization, but in order to take advantage of the abridged procedure, the generic manufacturer must demonstrate specific similarities, including bio equivalence, 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 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 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.

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 are 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 will apply 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 federal government is heavily involved in the operation of the industry, as it is the main purchaser of pharmaceutical products. The Australian federal government also regulates the quality, safety and efficacy of therapeutic goods.

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

For pharmaceutical products listed on the PBS, the price is determined through negotiations between the Pharmaceutical Benefits Pricing Authority (a governmental agency) and pharmaceutical 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

## **Table of Contents**

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 cGMP.

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

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

Labeling, packaging and advertising of pharmaceutical products are also regulated by the 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, which a person has manufactured (including manufacturing under license) or imported is defined as marketing, and in order to market pharmaceuticals, one has to obtain a license, which we refer to herein as a Marketing License, from the Minister of Health, Labour and Welfare, (Minister). A Marketing License includes a manufacturing license. There are two types of Marketing License according to the pharmaceuticals to be marketed. The authority to grant the Marketing License is delegated to prefectural governors and 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.

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

## **Table of Contents**

Approval remains with the Minister 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 Minister must seek the opinion of the Pharmaceutical Affairs and Food Sanitation Council.

The Pharmaceutical Law provides that when the pharmaceutical which 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 since it has harmful effects outweighing its indicated effects or performance, Marketing Approval shall not be granted.

The Minister 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 Minister, (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 Minister. The Minister 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 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.

## **Table of Contents**

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 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 Drug Enforcement Administration 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. 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. DMF s are confidential documents containing information on the manufacturing facility and processes used in the manufacture, characterization, quality control, packaging, and storage of an API. The DMF is reviewed for completeness by the FDA, or other similar regulatory agencies in other countries, in conjunction with applications filed by finished dosage manufacturers, requesting approval to use the given API in the production of their drug products. During the nine month period ended December 31, 2007, Matrix had filed 25 DMFs in the U.S. and 16 DMFs in the rest of the world.

## **Table of Contents**

### **Patents, Trademarks and Licenses**

We own or license a number of patents in the U.S. and foreign 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 prevent 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. For a discussion on market exclusivity, see "Product Development and Government Regulation" above.

In addition to patents and regulatory forms of exclusivity, we also market products with trademarks such as EprPen, Perforomist, Zylflo CR and Cyanokit. 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 Merck Generics 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, logical and marketing aspects including renaming certain of the acquired businesses, re-labeling certain products and incurring certain other related costs.

## **Table of Contents**

### **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.

#### *Matrix Segment*

Our APIs are sold primarily to generic finished dosage form manufacturers throughout the world.

#### *Specialty Segment*

Dey markets its products to the same types of customers as our Generics Segment. In addition, Dey markets its products to homecare customers.

Consistent with industry practice, we have a return policy that allows our customers to return product within a specified period prior to and subsequent to the expiration date. See the Application of Critical Accounting Policies section of our Management's Discussion and Analysis of Results of Operations and Financial Condition for a discussion of our 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 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; (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 a competitor's product has greater efficacy for treating a disease or particular form of 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

## **Table of Contents**

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 or decreased volume of sales, or both.

*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 UK 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 UK 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. Depending on the region, generic substitution by pharmacists is not officially permitted in Spain, making physicians and/or the pharmacist the key drivers of generic usage. Companies compete in Spain based on name recognition, service level, and a consistent supply of quality products.

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

*Japan.* The Japanese generics market is small by international standards. Historically, government initiatives have kept all drug prices low, resulting in little incentive for generic usage. More recently, 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 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.

## **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, coverage limits totaling \$20.0 million through the next \$35.0 million. Furthermore, outside of the U.S., we purchased a commercial insurance policy in each country with respect to our wholly-owned captive insurance subsidiary's first \$15.0 million of coverage that complies with the local country insurance laws. Additionally, certain subsidiaries maintain commercial coverage up to \$15.0 million with minimal retentions.

## **Table of Contents**

### **Raw Materials**

Mylan utilizes a global approach to managing relationships with its suppliers. The purchase of a controlling interest in Matrix provided Mylan with significant vertical integration opportunities that were significantly enhanced with the purchase of Merck Generics. 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 12,000 people globally. 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 that have employees who are unionized or part of works councils or trade unions. These worksites are primarily concentrated in central Europe and India.

### **Securities Exchange Act Reports**

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 file the information with, or furnish it to, the SEC. The contents of our website are not incorporated by reference in this Transition 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.

**OUR ACQUISITION OF MERCK GENERICS INVOLVES A NUMBER OF INTEGRATION RISKS. THESE RISKS COULD CAUSE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS, FINANCIAL**

**Table of Contents**

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

Our acquisition of Merck Generics involves a number of integration risks, such as:

- difficulties in successfully integrating the facilities, operations and personnel of Merck Generics 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 corporate infrastructure;
- difficulties in transitioning the 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, transaction and 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 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 MERCK GENERICS AND A CONTROLLING INTEREST IN MATRIX.**

The success of the acquisitions of Merck Generics 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 historical businesses of Mylan, Merck Generics and Matrix. 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 historical businesses of Mylan, Merck Generics and Matrix may not be combined in a manner that permits these cost 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.**

**Table of Contents**

We have grown very rapidly over the past few years, through our acquisitions of Merck Generics and a controlling interest in Matrix. This growth has put significant demands on our processes, systems and people. We expect to make significant 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 MERCK GENERICS 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 recently completed acquisitions of Merck Generics 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;

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;

natural disasters, including drought, floods and earthquakes in the countries in which we operate; and

communal disturbances, terrorist attacks, riots or regional hostilities in the countries in which we operate.

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 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, including, without limitation, nebivolol, for which we are dependent on our partner Forest Laboratories, which 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.

## **Table of Contents**

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 European Medicines Agency (or EMA) in the European Union (or 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. Bio equivalency studies conducted in one country may not be accepted in other countries, and the approval of a pharmaceutical product in one country does not necessarily mean that the product will be approved in another country. We, or a partner, may be unable to obtain requisite approvals on a timely basis for new generic or branded products that we may develop, license or otherwise acquire. Moreover, if we obtain regulatory approval for a drug it may be limited with respect to the indicated uses and delivery methods for which the drug may be marketed, which could in turn restrict our potential market for the drug. Also, for products pending approval, we may obtain raw materials or produce batches of inventory to be used in efficacy and bioequivalence testing, as well as in anticipation of the product's launch. In the event that regulatory approval is denied or delayed, we could be exposed to the risk of this inventory becoming obsolete. The timing and cost of obtaining regulatory approvals could adversely affect our product introduction plans, business, financial position and results of operations and could cause the market value of our common stock to decline. See Item 1. Business Product Development and Government Regulation.

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 Drug Price Competition and Patent Term Restoration Act of 1984, or the Waxman-Hatch 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.

**Table of Contents**

**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, 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:

- 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.**

**Table of Contents**

The generic pharmaceutical industry is highly competitive. We face competition from many U.S. and foreign manufacturers, some of whom are significantly larger than we are. Our competitors may be able to develop products and processes competitive with or superior to our own for many reasons, including that they may have:

proprietary processes or delivery systems;

larger research and development and marketing staffs;

larger production capabilities in a particular therapeutic area;

more experience in preclinical testing and human clinical trials;

more products; or

more experience in developing new drugs and greater financial resources, particularly with regard to manufacturers of branded products.

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

**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 cGMP. Compliance with cGMP 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. Regulator approval to manufacture a drug is site-specific. Failure to comply with cGMP regulations 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

**Table of Contents**

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 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, 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 HHS) 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, or AMP, based on the provisions of the Deficit Reduction Act of 2005, or DRA. One significant change as a result of the DRA is that AMP will 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, or 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

finer, 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

**Table of Contents**

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 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 (including, without limitation, nebulolol), 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;

**Table of Contents**

seeking to establish regulatory and legal obstacles that would make it more difficult to demonstrate bioequivalence;

initiating legislative efforts to limit the substitution of generic versions of brand pharmaceuticals;

filing suits for patent infringement that may delay regulatory approval of many generic products;

introducing next-generation products prior to the expiration of market exclusivity for the reference product, which often materially reduces the demand for the first generic product for which we seek regulatory approval;

obtaining extensions of market exclusivity by conducting clinical trials of brand drugs in pediatric populations or by other potential methods;

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

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

In the United States, some companies have lobbied Congress for amendments to the Waxman-Hatch 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 Merck Generics. Our high level of indebtedness could have important consequences, including:

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;

**Table of Contents**

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, if future debt financing is not available to us when required or is not available on acceptable terms, we may be unable to grow our business, take advantage of business opportunities, respond to competitive pressures or satisfy our obligations under our indebtedness. Any of the foregoing could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

**WE MAY DECIDE TO SELL ASSETS WHICH COULD ADVERSELY AFFECT OUR PROSPECTS AND OPPORTUNITIES FOR GROWTH, AND WHICH COULD AFFECT 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 we determine that such assets are not critical to our strategy, or if we believe the opportunity to monetize the asset is attractive, or in order to reduce indebtedness, or for other reasons. We have explored and will continue to explore the sale of certain non-core assets; in addition, we have recently announced that we are exploring strategic alternatives (including a divestiture) for our Dey business, and that Matrix is doing the same in regard to Docpharma. 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 dividends, prepay other indebtedness, sell assets, incur certain liens, enter into agreements with our affiliates or restricting our subsidiaries' ability to pay dividends, or merge or consolidate. In addition, our Senior Secured 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**

**Table of Contents**

**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 foreign and domestic suppliers.

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

We utilize controlled substances in certain of our current products and products in development and therefore must meet the requirements of the Controlled Substances Act of 1970 and the related regulations administered by the Drug Enforcement Administration, or 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 OUR MERCK GENERICS SUBSIDIARIES AWAY FROM THE MERCK NAME AND AWAY FROM SERVICES BEING PROVIDED BY MERCK KGAA MAY IMPOSE INHERENT RISKS OR 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 in company and product names in respect of the Merck Generics businesses for a two-year transitional period. 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 Merck Generics 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.

As part of the Merck Generics acquisition we entered into a transitional services agreement whereby Merck KGaA agreed to continue to provide certain services including accounting and information technology to Merck Generics for certain periods. The cost of transitioning such services from Merck KGaA to us during those periods as well as the

capital expenditures that may be required for system upgrades may be greater than we expect or result in other impediments to our business. Such costs or impediments 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.

In addition, in limited circumstances, entities we acquired in the acquisition of Merck Generics are party to litigation and/or subject to investigation in matters under which we are entitled to indemnification by Merck KGaA.

**Table of Contents**

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.

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

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

**WE HAVE A LIMITED NUMBER OF MANUFACTURING FACILITIES PRODUCING A SUBSTANTIAL PORTION OF OUR PRODUCTS. PRODUCTION AT ANY ONE OF THESE FACILITIES COULD BE INTERRUPTED, WHICH COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS, FINANCIAL POSITION AND RESULTS OF OPERATIONS AND COULD CAUSE THE MARKET VALUE OF OUR COMMON STOCK TO DECLINE.**

A substantial portion of our capacity as well as our current production is attributable to a limited number of manufacturing facilities. A significant disruption at any one of those facilities, even on a short-term basis, could impair our ability to produce and ship products to the market on a timely basis, which could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

**WE MAY EXPERIENCE DECLINES IN THE SALES VOLUME AND PRICES OF OUR PRODUCTS AS THE RESULT OF THE CONTINUING TREND TOWARD CONSOLIDATION OF CERTAIN CUSTOMER GROUPS, SUCH AS THE WHOLESALE DRUG DISTRIBUTION AND RETAIL PHARMACY INDUSTRIES, AS WELL AS THE EMERGENCE OF LARGE BUYING GROUPS. THE RESULT OF SUCH DEVELOPMENTS COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS, FINANCIAL POSITION AND RESULTS OF OPERATIONS AND COULD CAUSE THE MARKET VALUE OF OUR COMMON STOCK TO DECLINE.**

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

## **Table of Contents**

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 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. 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 UK National Health Service and the German statutory health insurance scheme) and private health insurers and other organizations, such as health maintenance organizations, or 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. The Act to Increase Competition in the Statutory Health Insurance Scheme provides, inter alia: (i) in addition to the existing reference price scheme, SHI funds will impose reimbursement caps on innovative drugs; (ii) SHI-funds will receive a rebate for generic drugs corresponding to 10% of the selling price, excluding VAT (this does not apply to generic drugs the price of which is at least 30% below the reference price); (iii) SHI funds will receive a rebate for generic drugs corresponding to 16% of the selling price, excluding VAT, for generics which are not listed in the inventory of groups of pharmaceuticals with a fixed price to be reimbursed by the statutory health insurance scheme; and (iv) new incentives for individual rebate contracts between pharmaceutical companies and single SHI funds. 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 UK, the Office of Fair Trading produced recommendations in February 2007 that suggested that the UK should move towards a value based pricing structure for the reimbursement of pharmaceutical products from 2010. If these recommendations are accepted and lead to change in the system of reimbursement, this could lead to increased pressure on competition and reimbursement margins. This could have a material adverse effect on our

**Table of Contents**

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 PRESCRIPTION DRUGS 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.

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.

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

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

**WE ENTER INTO VARIOUS AGREEMENTS IN THE NORMAL COURSE OF BUSINESS WHICH PERIODICALLY INCORPORATE PROVISIONS WHEREBY WE INDEMNIFY THE OTHER PARTY TO THE AGREEMENT. IN THE EVENT THAT WE WOULD HAVE TO PERFORM UNDER THESE INDEMNIFICATION PROVISIONS, IT COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS, FINANCIAL POSITION AND RESULTS OF OPERATIONS AND COULD CAUSE THE MARKET VALUE OF OUR COMMON STOCK TO DECLINE.**

In the normal course of business, we periodically enter into employment, legal settlement, and other agreements which incorporate indemnification provisions. We maintain insurance coverage which we believe will effectively mitigate

our obligations under certain of these indemnification provisions. However, should our obligation under an indemnification provision exceed our coverage or should coverage be denied, our business, financial position and results of operations could be materially 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**

**Table of Contents**

**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 HAVE BEGUN THE IMPLEMENTATION OF AN ENTERPRISE RESOURCE PLANNING SYSTEM. AS WITH ANY IMPLEMENTATION OF A SIGNIFICANT NEW SYSTEM, 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 have begun the implementation of an enterprise resource planning, or ERP, system in the United States to enhance operating efficiencies and provide more effective management of our business operations. Implementations of 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 implementation, 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.

**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 we operate, which are designed to promote foreign investment generally, including significant tax incentives, liberalized import and export duties and preferential rules on foreign

**Table of Contents**

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. Our ability to recruit, train and retain qualified employees and develop and operate our 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, indebtedness and our costs will be denominated in foreign currencies including the Australian dollar, the British pound, the Canadian dollar, the Euro, the Indian rupee and the Japanese Yen. We report our financial results in U.S. dollars. Our results of operations 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 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 large part on our ability to obtain, maintain and enforce patents, and protect trade secrets, know-how and other proprietary information. Our ability to commercialize any branded product successfully will largely depend upon our 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

**Table of Contents**

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 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:

limited patent life;

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, new SEC regulations and the New York Stock Exchange rules. In particular, Section 404 of the Sarbanes-Oxley Act of 2002 requires management's annual review and evaluation of our internal control over financial reporting and attestations as to the effectiveness of these controls by our independent registered public accounting firm. If we fail to maintain the adequacy of our internal controls, we may not be able to ensure that



we can conclude on an ongoing basis that we have effective internal control over financial reporting. Additionally, internal control over financial reporting may not prevent or detect misstatements because of its inherent limitations, including the possibility of human error, the circumvention or overriding of controls, or fraud. Therefore, even effective internal controls can provide only reasonable assurance with respect to the preparation and fair presentation of financial statements. In addition, projections of any evaluation of effectiveness of internal control over financial reporting to future periods are subject to the risk that the control may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. If the Company fails to maintain the adequacy of its internal controls, including any failure to

**Table of Contents**

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.

On October 2, 2007 we acquired Merck Generics. For purposes of management's evaluation of our internal control over financial reporting as of December 31, 2007, we elected to exclude Merck Generics from the scope of management's assessment as permitted by guidance provided by the SEC.

**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, or 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 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
		Leased	Warehousing, Administrative
	Illinois	Owned	Manufacturing, Warehousing, Administrative
	New York	Leased	Administrative
	Texas	Owned	Manufacturing, Warehousing
	Vermont	Owned	Manufacturing, R&D, Warehousing, Administrative
	Pennsylvania	Leased	Administrative
	Puerto Rico	Owned	Manufacturing, Warehousing, Administrative
	Germany	Leased	Administrative
	France	Owned	Warehousing
		Leased	Administrative
	United Kingdom	Owned	Manufacturing, R&D
		Leased	Manufacturing, R&D, Warehousing, Administrative
	Ireland	Owned	Manufacturing, R&D, Warehousing, Administrative
		Leased	Warehousing, Administrative
	Sweden	Leased	Administrative
	Finland	Leased	Administrative
	Denmark	Leased	Administrative
	Australia	Owned	Manufacturing, R&D, Distribution, Warehousing, Administrative
		Leased	Distribution, Administrative
	Austria	Leased	Administrative
	Belgium	Leased	Administrative
	Netherlands	Leased	Distribution, Warehousing, Administrative
	Italy	Leased	Administrative
	South Africa	Leased	Manufacturing, Administrative
	Morocco	Leased	Administrative
	Portugal	Leased	Administrative
	Spain	Owned	Manufacturing
		Leased	Administrative
	Greece	Leased	Administrative
	Canada	Owned	Manufacturing, R&D, Distribution, Warehousing, Administrative
	Leased	Distribution, Warehousing	
New Zealand	Owned	Manufacturing, R&D	
	Leased	Manufacturing, Distribution, Warehousing, Administration	



**Table of Contents**

<b>Primary Segment</b>	<b>Location</b>	<b>Status</b>	<b>Primary Use</b>
<b>Specialty Segment</b>	Japan	Owned Leased	Manufacturing, R&D, Administrative Warehousing, Administrative
	California	Owned	Manufacturing, R&D, Warehousing, Administrative
<b>Matrix Segment</b>	Texas	Leased	Distribution, Warehousing
	China	Owned	Manufacturing, Warehousing, Administrative
<b>Corporate/Other</b>	India	Owned	Manufacturing, R&D, Warehousing, Administrative
		Leased	R&D, Administrative
	Belgium	Leased	R&D, Distribution, Warehousing, Administrative
	Netherlands	Leased	Distribution, Warehousing, Administrative
	Luxembourg	Leased	Warehousing, Administrative
	France	Leased	Administrative
	Switzerland	Leased	Administrative
	Pennsylvania	Owned	Administrative

We believe that all facilities are in good operating condition, the machinery and equipment are well-maintained, the facilities are suitable for their intended purposes and they have capacities adequate for current operations.

**ITEM 3. Legal Proceedings***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 we acquired Merck Generics. An adverse outcome in any of these proceedings could have a material adverse effect on the Company's financial position and results of operations.

*Omeprazole*

In fiscal 2001, Mylan Pharmaceuticals Inc. ( MPI ) filed an Abbreviated New Drug Application ( ANDA ) seeking approval from the U.S. Food and Drug Administration ( FDA ) to manufacture, market and sell omeprazole delayed-release capsules and 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 Inc. ( 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, which could result in treble damages, injunctive relief, attorneys' fees, costs of litigation and such further relief as the court deems just and proper. MPI has certain indemnity obligations to Esteve in connection with this litigation. MPI, Esteve and the other

generic manufacturers who are co-defendants in the case filed motions for summary judgment of non-infringement and patent invalidity. On January 12, 2006, those motions were denied. 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

**Table of Contents**

Mylan's/Esteve's products. On July 18, 2007, AstraZeneca appealed the decision to the United States Court of Appeals for the Federal Circuit.

*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 ( D.C. ) in the amount of approximately \$12 million which has been accrued for by the Company. The jury found 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 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 \$7.5 million plus additional interest accruing daily. The Company and its co-defendants have appealed to the U.S. Court of Appeals for the D.C. Circuit.

*Pricing and Medicaid Litigation*

On June 26, 2003, MPI and UDL Laboratories Inc. ( 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, 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 a series of 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 ( AWP ) 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, 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, with the exception of the Florida, Iowa, Idaho, South Carolina and Utah AG actions, Mylan, MPI



and/or UDL have answered the respective complaints denying liability. Mylan and its subsidiaries intend to defend each of these actions vigorously.

In addition, by letter dated January 12, 2005, MPI was notified by the U.S. Department of Justice of an investigation concerning MPI's calculations of Medicaid drug rebates. MPI is cooperating fully with the government's investigation.

## **Table of Contents**

Dey, Inc. has also been named in suits brought by the state AG's of Alaska, Arizona, California, Florida, Illinois, Iowa, Kentucky, Mississippi, 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 and a number of these cases remain pending. Additionally, U.S. federal government filed a claim against Dey, Inc. in September 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.

### *Modafinil Antitrust Litigation and FTC Inquiry*

Beginning in April 2006, Mylan, along with four other drug manufacturers, has been named in a series of 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 Mylan Technologies Inc. (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. Mylan is not named as a defendant in the lawsuit, although the complaint includes allegations pertaining to the Mylan/Cephalon settlement.

### *Merck Generics Litigation*

Generics (UK) Ltd. has been alleged of having been involved in pricing agreements pertaining to certain drugs during the years 1996 and 2000. Generics (UK) Ltd. was able to settle claims for damages asserted by the Health Service in England and Wales out of court, which does not constitute any admission of liability. Additional claims were filed against Generics (UK) Ltd. by health authorities in Scotland and Northern Ireland totaling £20.0 (\$39.9) million plus interest. In addition to these civil claims, criminal proceedings were also filed in Southwark Crown Court in April 2006 against Generics (UK) Ltd. and the people responsible for running this company.

The Company has approximately \$132.3 million recorded in other liabilities related to the litigation involving Dey and Generics (UK) Ltd. As stated above, in conjunction with the Merck Generics acquisition, this litigation has been indemnified by Merck KGaA under the Share Purchase Agreement. As a result, the Company has recorded approximately \$137.1 million in other assets.

### *Other Litigation*

The Company is involved in various other legal proceedings that are considered normal to its business. While it is not feasible to predict the ultimate outcome of such other proceedings, the Company believes that the ultimate outcome of such other proceedings will not have a material adverse effect on its financial position or results of operations.

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

None.

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

Our common stock is traded on the New York Stock Exchange 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>Nine Months Ended December 31, 2007</b>	<b>High</b>	<b>Low</b>
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
<b>Fiscal Year Ended March 31, 2007</b>	<b>High</b>	<b>Low</b>
Three months ended June 30, 2006	\$ 23.73	\$ 19.72
Three months ended September 30, 2006	23.49	18.65
Three months ended December 31, 2006	22.10	19.72
Three months ended March 31, 2007	22.75	19.18

As of February 19, 2008, there were approximately 133,137 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 Merck Generics, 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, 2007:

<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 security holders	21,893,772	\$ 15.37	10,489,164
Equity compensation plans not approved by security holders			
Total	21,893,772	\$ 15.37	10,489,164

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

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. 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 five fiscal years ended March 31, 2007, and the nine-month period ended December 31, 2007 of \$100 invested on March 31, 2002 in Mylan's Common Stock, the Standard & Poor's 500 Composite Index and the Dow Jones U.S. Pharmaceuticals Index.

\* \$100 invested on 3/31/02 in stock or index-including reinvestment of dividends. Fiscal year ending December 31.

	<b>3/02</b>	<b>3/03</b>	<b>3/04</b>	<b>3/05</b>	<b>3/06</b>	<b>3/07</b>	<b>12/07</b>
Mylan Inc.	100.00	147.15	175.26	137.53	183.76	167.97	112.08
S&P 500	100.00	75.24	101.66	108.47	121.19	135.52	142.06
Dow Jones US Pharmaceuticals	100.00	81.36	86.55	80.77	82.37	91.59	95.42

**Table of Contents****PART II****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 Transition Report on 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 in the U.S. Dollar ( USD ). The functional currency of each of Mylan's other subsidiaries (primarily in Western Europe, Canada and Asia Pacific) is the respective local currency.

	<b>Nine Months Ended<sup>(1)</sup> December 31, 2007</b>	<b>2007<sup>(2)</sup></b>	<b>Fiscal Year Ended March 31,</b>		
			<b>2006</b>	<b>2005</b>	<b>2004</b>
<i>(in thousands, except share and per share amounts)</i>					
<b>Statements of Operations:</b>					
Total revenues	\$ 2,178,761	\$ 1,611,819	\$ 1,257,164	\$ 1,253,374	\$ 1,374,617
Cost of sales	1,304,313	768,151	629,548	629,834	612,149
Gross profit	874,448	843,668	627,616	623,540	762,468
<b>Operating expenses:</b>					
Research and development	146,063	103,692	102,431	88,254	100,813
Acquired in-process research and development	1,269,036	147,000			
Selling, general and administrative	449,598	215,538	225,380	259,105	201,612
Litigation settlements, net	(1,984)	(50,116)	12,417	(25,990)	(34,758)
(Loss) earnings from operations	(988,265)	427,554	287,388	302,171	494,801
Interest expense	179,410	52,276	31,285		
Other income, net	86,611	50,234	18,502	10,076	17,807
(Loss) earnings before income taxes and minority interest	(1,081,064)	425,512	274,605	312,247	512,608
Provision for income taxes	60,073	208,017	90,063	108,655	177,999
Minority interest	(3,112)	211			
Net (loss) earnings	(1,138,025)	217,284	184,542	203,592	334,609
Preferred dividends	15,999				
Net (loss) earnings available to common shareholders	\$ (1,154,024)	\$ 217,284	\$ 184,542	\$ 203,592	\$ 334,609

Selected Balance Sheet data:

Edgar Filing: MYLAN INC. - Form 10-KT/A

Total assets	\$	11,353,176	\$	4,253,867	\$	1,870,526	\$	2,135,673	\$	1,885,061
Working capital		1,056,950		1,711,509		926,650		1,282,945		1,144,073
Short-term borrowings		144,355		108,259						
Long-term debt		4,706,716		1,654,932		685,188				
Total shareholders equity		3,403,426		1,648,860		787,651		1,845,936		1,659,788
Per common share data:										
Net (loss) earnings available to common shareholders										
Basic	\$	(4.49)	\$	1.01	\$	0.80	\$	0.76	\$	1.24
Diluted	\$	(4.49)	\$	0.99	\$	0.79	\$	0.74	\$	1.21
Cash dividends declared and paid	\$	0.06	\$	0.24	\$	0.24	\$	0.12	\$	0.10
Weighted average common shares outstanding:										
Basic		257,150		215,096		229,389		268,985		268,931
Diluted		257,150		219,120		234,209		273,621		276,318

(1) The nine months ended December 31, 2007 includes the results of the Merck Generics acquisition from October 2, 2007. In addition to the write-off of acquired in-process research and development (\$1.27 billion),



## **Table of Contents**

cost of sales includes approximately \$148.9 million related to the amortization of purchased intangibles and the amortization of the inventory step-up associated with the Merck Generics and Matrix acquisition.

- (2) Fiscal 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 (\$147.0 million), cost of sales includes approximately \$17.6 million related to the amortization of intangibles and the inventory step-up associated with the acquisition. Fiscal 2007 also includes \$22.2 million of stock-based compensation expense from the adoption of SFAS No. 123 (revised 2004), Share-Based Payment ( SFAS No. 123R ) on April 1, 2006.

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

The following discussion and analysis, as well as other sections in this Transition Report, should be read in conjunction with the Consolidated Financial Statements and related Notes to Consolidated Financial Statements included elsewhere in this report.

This discussion and analysis 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 words or 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 under Risk Factors in ITEM 1A. The Company undertakes no obligation to update any forward-looking statements for revisions or changes after the filing 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 Merck Generics in the current year, as further discussed below, and the acquisition of a controlling interest in Matrix in the prior year, we are the third largest generic pharmaceutical company in the world based on 2006 combined calendar year revenues, a leader in branded specialty pharmaceuticals and the second largest active pharmaceutical ingredient, or API, manufacturer with respect to the number of drug master files, or DMFs, filed with regulatory agencies. We hold a leading sales position in four of the world's six largest generic pharmaceutical markets: the United States, the United Kingdom, France and Japan, and we also hold leading sales positions in several other key generics markets, including Australia, Belgium, Italy, Portugal and Spain.

### **Change in Fiscal Year**

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

Transition Period or current period April 1, 2007 through December 31, 2007.

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

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

Edgar Filing: MYLAN INC. - Form 10-KT/A

fiscal 2006 April 1, 2005 through March 31, 2006.

fiscal 2005 April 1, 2004 through March 31, 2005.

The above periods include Matrix operations from January 8, 2007 and Merck Generics operations from October 2, 2007.

## **Table of Contents**

### **Acquisition of Generics Business of Merck KGaA**

On October 2, 2007, Mylan completed its acquisition of the generic pharmaceuticals business of Merck KGaA ( Merck Generics ) in an all-cash transaction. The net purchase price was approximately \$7.0 billion. Mylan has accounted for this transaction as a purchase under Statement of Financial Accounting Standards ( SFAS ) No. 141, *Business Combinations*, and has consolidated the results of operations of Merck Generics from October 2, 2007. The combination of Mylan and Merck Generics creates a vertically and horizontally integrated generics and specialty pharmaceuticals leader with a diversified revenue base and a global footprint.

The acquisition of Merck Generics was financed through existing cash and several new borrowing arrangements which the Company entered into in October of 2007. See *Liquidity and Capital Resources* for further discussion.

### **Segments**

Mylan previously had two reportable segments, the Mylan Segment and the Matrix Segment . With the acquisition of Merck Generics, Mylan now has three reportable segments: the Generics Segment, the Specialty Segment, and the Matrix Segment. The former Mylan Segment is included within the Generics Segment. Additionally, certain general and administrative expenses, as well as litigation settlements, and non-operating income and expenses are reported in Corporate/Other. In accordance with SFAS No. 131, *Disclosures about Segments of an Enterprise and Related Information*, information for earlier periods has been recast.

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 ). The amortization of intangible assets as well as certain purchase accounting related items such as the write-off of in-process research and development and the amortization of the inventory step-up are excluded from segment profitability. These charges, along with corporate overhead, intercompany eliminations and other charges not directly attributable to any one segment, are included in Corporate/Other.

### **Equity Offerings**

In November and December 2007, the Company completed the sale of 2.14 million shares of 6.50% mandatory convertible preferred stock at \$1,000 per share and 55.4 million shares of common stock at \$14.00 per share pursuant to a shelf registration statement previously filed with the Securities and Exchange Commission. These offerings generated net proceeds, after underwriting discounts and expenses, totalling approximately \$2.82 billion, which was used along with cash on hand to repay \$2.85 billion of bridge loans that were borrowed to finance in part the Company s acquisition of Merck Generics. See *Liquidity and Capital Resources* for further discussion.

The preferred stock will pay dividends, when declared by the Board, at a rate of 6.50% percent 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 Mylan 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 Mylan common stock. The conversion rate will be subject to anti-dilution adjustments in certain circumstances. Holders may elect to convert at any time prior to November 15, 2010 at the minimum conversion rate of 58.5480 shares of common stock for each share of preferred stock. The preferred stock is listed on the New York Stock Exchange under the symbol MYLPrA.

### **Product Opportunities**

On October 4, 2007, the Company entered into an agreement to settle pending litigation with UCB Societe Anonyme and UCB Pharma Inc. (collectively, "UCB") relating to levetiracetam tablets, 250mg, 500mg and 750mg, the generic version of UCB's Keppra®. Pursuant to the settlement, Mylan has the right to market the 250mg, 500mg and 750mg strengths of levetiracetam tablets in the United States on November 1, 2008, provided that UCB obtains pediatric exclusivity for Keppra and Mylan's abbreviated new drug application ("ANDA") obtains final approval from the Food and Drug Administration ("FDA"). If granted, pediatric exclusivity relating to the '639 patent would extend to January 14, 2009. Mylan's entry into the market could come sooner than November 1, 2008, if the FDA

## **Table of Contents**

does not grant UCB pediatric exclusivity. Levetiracetam Tablets had U.S. sales of approximately \$742.0 million for the 12 months ended June 30, 2007, for these three strengths.

In December 2007, Matrix received tentative approval from the FDA under the President's Emergency Plan for AIDS Relief (PEPFAR) for its ANDA for tenofovir disoproxil fumarate tablets, 300 mg. Matrix's tenofovir disoproxil fumarate is the first and only generic tentative approval of Gilead Sciences Inc.'s Viread Tablets, 300 mg. Matrix's ANDA was tentatively approved in less than six months and is the seventh PEPFAR tentative approval earned by Matrix within the last 12 months. Under PEPFAR, a tentative approval means that a company can immediately sell an HIV/AIDS treatment in certain countries outside of the United States. Although existing patents and/or marketing exclusivity prevent the approval of the product in the United States, a tentative approval indicates that the product meets all safety, efficacy and manufacturing quality standards for marketing in the United States, which helps to ensure AIDS patients abroad who receive these medications get the same quality product as the American public.

Mylan has entered into a patent license and settlement agreement with GlaxoSmithKline (GSK) relating to Paroxetine Hydrochloride (HCl) Extended-release (ER) Tablets, the generic version of GSK's Paxil CR. Under the agreement and an associated supply and distribution agreement, Mylan is provided patent licenses and the right to market all three strengths of Paroxetine HCl ER Tablets, 12.5 mg, 25 mg and 37.5 mg, beginning no later than October 1, 2008. Paroxetine HCl ER Tablets had U.S. sales of approximately \$342.0 million for the 12 months ending June 30, 2007, for all three strengths. Mylan was the first company to file an ANDA containing a paragraph IV certification covering the 12.5 mg and 25 mg strengths. Upon receipt of final approval from the U.S. Food and Drug Administration on June 29, 2007, Mylan became eligible for a 180-day period of marketing exclusivity for these two tablet strengths.

## **Strategic Initiatives**

On February 27, 2008, Mylan executed an agreement with Forest Laboratories, whereby Mylan sold its rights to Nebivolol, an FDA approved product for the treatment of hypertension which is marketed by Forest under the Brand name Bystolic(TM). Mylan will receive a one-time cash payment of \$370.0 million (within ten business days from the execution of the agreement) and will retain its contractual royalties for three years, through calendar 2010.

We have an ongoing process that includes a review of our operations. These alternatives may include forming strategic alliances or divestitures. As part of this process, we are initially focused on Dey, our specialty branded business and Matrix is focusing on Docpharma, their commercial operations in the Benelux countries. To that end, we may engage outside advisors to assist us in considering our alternatives, including the potential sale of one or more of these businesses.

## **Financial Summary**

Total revenues for the transition period were \$2.18 billion. For the comparable nine-month period, total revenues were \$1.12 billion. This represents an increase of 94% in total revenues. Consolidated gross profit for the transition period was \$874.4 million compared to \$608.8 million in the comparable nine-month period, an increase of 44%. In the transition period, an operating loss of \$988.3 million was realized compared to operating income of \$435.3 million in the comparable nine-month period.

The net loss available to common shareholders for the current period was \$1.15 billion compared to net earnings of \$288.6 million in the prior period. This translates into a loss per diluted share of \$4.49 for the nine-months ended December 31, 2007, compared to earnings per diluted share of \$1.34 in the comparable nine-month period. Comparability of results between these two periods is affected by the following items:

*Transition Period:*

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

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

**Table of Contents**

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 Merck Generics acquisition;

Amortization expense related to intangible assets related to the Merck Generics and Matrix acquisitions of \$100.7 million (pre-tax);

Amortization of the inventory step-up related to the Merck Generics and Matrix acquisitions of \$44.4 million (pre-tax); and

A \$16.0 million (pre-tax and after-tax) dividend on the 6.50% mandatory convertible preferred stock.

*Comparable Nine-Month Period:*

Net gains from the settlement of litigation in the amount of \$46.2 million (pre-tax); and

A gain on a foreign currency exchange forward contract related to the acquisition of Matrix in the amount of \$17.5 million (pre-tax).

A more detailed discussion of the Company's financial results can be found below under the section titled *Results of Operations*.

**Results of Operations**

**Transition Period Ended December 31, 2007, Compared to Comparable Nine-Month Period Ended 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 Merck Generics 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 Merck Generics 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 current period, excluding amounts related to the acquisitions of Merck Generics and Matrix, was comprised of fentanyl and new products, including amolodipine. 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



**Table of Contents**

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 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 Merck Generics. 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 Merck Generics. 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 Merck Generiques 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 U.K. where wholesalers decreased their orders in anticipation of more favorable rebate contracts that are scheduled to take effect in the first quarter of calendar year 2008. 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 40% 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 Merck Generics. 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.

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 will be 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.

## **Table of Contents**

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 Merck Generics. 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.

### **Specialty Segment**

For the transition period, the Specialty Segment reported total revenues of \$102.1 million. The Specialty Segment consists primarily of Dey L.P. ( Dey ), an entity acquired as part of the Merck Generics 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 are expected to decline 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 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 Merck Generics.

### **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 Merck Generics.

### **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 Merck Generics 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 Merck Generics 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.

**Table of Contents**

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 Merck Generics. The increase in payroll and related costs is principally attributable to the build-up of additional corporate infrastructure as a direct result of the Merck Generics acquisition.

*Litigation, net*

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

*Interest Expense*

Interest expense for the transition period totaled \$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 Merck Generics. 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 Merck Generics 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, 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 Merck Generics, 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 Compared to Fiscal 2006**

*Total Revenues and Gross Profit*

Total revenues for fiscal 2007 were \$1.61 billion compared to \$1.26 billion for fiscal 2006, an increase of \$354.7 million or 28%. Generics Segment total revenues were \$1.53 billion, and Matrix Segment total revenues were \$79.4 million. In arriving at net revenues, gross revenues are reduced by provisions for estimates, including

## **Table of Contents**

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 fiscal year ended March 31, 2007, the most significant amounts charged against gross revenues were for chargebacks in the amount of \$1.19 billion and customer performance and promotions in the amount of \$180.7 million. For fiscal 2006, chargebacks of \$1.11 billion and customer performance and promotions of \$160.8 million were charged against gross revenues. Customer performance and promotions include direct rebates as well as promotional programs.

For the Generics Segment, net revenues increased by \$267.5 million or 22% compared to fiscal 2006 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 continues to be 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 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 increased by \$7.7 million from \$17.2 million in fiscal 2006 to \$24.9 million for the current fiscal year. This increase was 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% 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 increased 34% or \$216.1 million to \$843.7 million from \$627.6 million, and gross margins increased to 52.3% from 49.9%. For the Generics Segment, gross profit was \$846.6 million compared to \$627.6 million in fiscal 2006, while gross margins increased to 55.2% from 49.9%. 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 research and development ( R&D ) expense for fiscal 2007 was \$103.7 million compared to \$102.4 million in fiscal 2006, which represents an increase of \$1.3 million or 1%. Matrix Segment R&D expense was \$12.7 million for fiscal 2007. Excluding this, R&D expense decreased by \$11.4 million or 11%. The Generic Segment had R&D expense of \$81.8 million in fiscal 2007 compared to \$101.1 million in fiscal 2006. The overall decrease is primarily the result of the outlicensing of nebivolol, which occurred late in fiscal 2006.



## **Table of Contents**

Additionally, during the fourth quarter, 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.

Selling, general and administrative ( SG&A ) expense for fiscal 2007 was \$215.5 million compared to \$225.4 million in fiscal 2006, a decrease of \$9.8 million or 4%. Generics Segment SG&A expense was \$65.4 million, a decrease of \$10.4 million from fiscal 2006. This decrease is primarily the result of 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 compared to \$149.6 million in the prior year, a decrease of \$5.2 million or 4%. Prior year Corporate and Other SG&A included \$19.9 million of restructuring costs associated with the closure of Mylan Bertek, which 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 the Matrix Segment, SG&A expense was \$5.8 million in fiscal 2007.

### *Litigation, net*

Net favorable settlements of \$50.1 million were recorded in fiscal 2007. In the same period of the prior year, litigation, net was a \$12.4 million charge of which \$12.0 million was for a contingent liability with respect to the Company's previously disclosed lorazepam and clorazepate product litigation.

### *Interest Expense*

Interest expense for fiscal 2007 totaled \$52.3 million compared to \$31.3 million for the same period of the prior year. The Company has had its financing outstanding for all of fiscal 2007, while it was only completed during the second quarter of fiscal 2006. Also 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.

### *Other Income, net*

Other income, net was \$50.2 million for fiscal 2007 compared to \$18.5 million in the same prior year period. The change is primarily the result of 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 Somerset Pharmaceuticals, Inc., in which Mylan owns a 50% equity interest and accounts for this investment using the equity method of accounting. The amount in excess of the carrying value of our investment in Somerset, approximately \$5.0 million, was recorded as equity income.

### *Income Tax Expense*

The Company's effective tax rate increased for fiscal 2007 to 48.9% from 32.8% in fiscal 2006. This increase is primarily due to the acquisition of Matrix and the related non-deductible \$147.0 million charge related to acquired in-process R&D. In addition, higher pre-tax income for fiscal 2007 resulted in higher state taxes while state credits remained relatively fixed. Additionally, the favorable impact of federal tax credits on the effective tax rate was less significant in fiscal 2007 primarily because of the expiration of the Section 936 credits and lower R&D credits when compared to the previous fiscal year.

## **Liquidity and Capital Resources**

Cash flows from operating activities were \$167.7 million for the transition period, consisting primarily of non-cash add-backs for acquired in-process research and development and depreciation and amortization, partially offset by a net decrease in operating assets and liabilities. The most significant changes in operating assets and

**Table of Contents**

liabilities were seen in accounts receivable, due primarily to the timing of customer payments and the issuance of credits, and accounts payable which decreased due to the timing of payments.

Cash used in investing activities for the nine months ended December 31, 2007 was \$7.0 billion. 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 \$82.1 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 the nine months ended December 31, 2007 were \$110.5 million. These expenditures were incurred primarily for equipment, including with respect to the Company's previously announced planned expansions. Also included in investing activities was \$7.0 billion paid to acquire Merck Generics.

Cash provided by financing activities was \$6.1 billion for the nine months ended December 31, 2007. Mylan generated \$2.8 billion through the issuance of common stock and mandatorily convertible preferred stock. Mylan sold 55.4 million shares of common stock at a price of \$14.00 per share, and approximately 2.14 million shares of 6.50% mandatory convertible preferred stock at \$1,000 per share on November 19, 2007. Proceeds from the issuance of common and preferred stock are shown net of underwriters discounts and offering expenses of approximately \$93.2 million.

The preferred stock will pay, when declared by the Board of Directors, dividends at a rate of 6.50% percent 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 when declared by the Board of Directors. The first dividend date was February 15, 2008, at which time the Company paid \$33.2 million in cash. 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. Under certain circumstances, we 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.

In conjunction with the closing of the Merck Generics acquisition 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 Loan (the "U.S. Tranche B Term Loans"), and the Euro Borrower borrowed approximately 1.1 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 Merck Generics, (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 outstanding 5.750% Senior Notes due 2010 and the 6.375% Senior Notes due 2015, collectively the "Senior Notes", tendered pursuant to the previously announced 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 Merck

Generics acquisition, the Company borrowed \$325.0 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

**Table of Contents**

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. On October 19, 2007, the Company paid \$25.0 million on the Revolving Facility, reducing the principle amount due to \$300.0 million.

The U.S. Tranche A Term Loans and 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 Term Loans currently bear interest at the Euro Interbank Offered Rate ( 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 2.75% 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 1.75% 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 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 are not tested earlier than the quarter ended June 30, 2008.

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 mature on October 2, 2013. The U.S. Tranche B Term Loans and the Euro Term Loans mature on October 2, 2014. The U.S. Tranche B Term Loans and the Euro Tranche B Term Loans (original 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 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 transactions related to the acquisition of Merck Generics.

The Interim Term Loans bore interest at LIBOR (determined in accordance with the Interim Credit Agreement) plus 4.50% per annum. On November 19, 2007, the Interim Term Loans were repaid using primarily the proceeds received from the preferred stock and common stock issuances of approximately \$2.82 billion. The

**Table of Contents**

remaining \$28.1 million was paid using existing cash of the Company. The Company incurred approximately \$37.5 million in interest expense and expensed \$14.3 million in financing fees related to the Interim Term Loans.

In conjunction with the repayment of certain 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 new financing for the Merck Generics 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.

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 Senior Credit Agreement as set out below.

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

The new 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 Euro Tranche A Term Loans mature on October 2, 2013. The Euro Tranche A Term Loans require amortization payments of 4.4 (\$6.5) million per quarter in 2008, 8.8 (\$13.0) million per quarter in 2009, 13.1 (\$19.3) million per quarter in 2010, 17.5 (\$25.8) million per quarter in 2011, 21.9 (\$32.3) million per quarter in 2012 and 21.9 (\$32.3) million per quarter in 2013. In connection with the decrease in the aggregate principal amount of the U.S. Tranche A Term Loans, the amortization payments required with respect to the U.S. Tranche A Term Loans have been revised to \$3.9 million per quarter in 2008, \$7.8 million per quarter in 2009, \$11.7 million per quarter in 2010, \$15.6 million per quarter in 2011, \$19.5 million per quarter in 2012 and \$19.5 million per quarter in 2013.

The Amended Senior Credit Agreement adds 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.

The interest rate in effect at December 31, 2007, on the outstanding borrowings under the U.S. Tranche A Term Loan was 8.31% and for the U.S. Tranche B Term Loans was 8.24% at December 31, 2007. The interest rate in effect at December 31, 2007, on the outstanding borrowings under the Euro Tranche A Term Loans and Euro Tranche B Term Loans was 7.75%.

We executed \$1.0 billion of notional interest rate swaps in order to fix the interest rate on a portion of our U.S. dollar debt. These swaps are designated as a cash flow hedge of expected future borrowings under the Senior Credit Agreement and to fix a rate of 7.37% until December 2010.

Our Amended Senior Credit Agreement imposes significant operating and financial restrictions on us. These restrictions limit our ability to, among other things, incur additional indebtedness, make investments, pay dividends, prepay other indebtedness, sell assets, incur certain liens, enter into agreements with our affiliates or restricting our subsidiaries' ability to pay dividends, or 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



**Table of Contents**

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.

Also included in cash flows from financing activities are proceeds of \$7.7 million from the exercise of stock options and cash dividends paid on common stock of \$29.8 million. As the Company announced on May 12, 2007, in conjunction with the acquisition of Merck KGaA's generic business, the Company has suspended its dividend on its common stock.

The Company also has approximately \$41.0 million of auction rate securities at December 31, 2007. Subsequent to December 31, approximately \$32.0 million of these securities were sold at par value. The remainder of these securities are scheduled to reset at auction in May 2008. During the nine months ended December 31, 2007, no auctions failed.

The Company is involved in various legal proceedings that are considered normal to its business (see Note 17 to the Consolidated Financial Statements). While it is not feasible 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.

The Company is actively pursuing, and is currently involved in, joint projects related to the development, distribution and marketing of both generic and brand 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, the Company is evaluating potential divestitures of products and businesses as part of its future strategy. Any divestitures could impact future liquidity.

**Contractual Obligations**

The following table summarizes our contractual obligations at December 31, 2007 and the effect that such obligations are expected to have on our liquidity and cash flows in future periods:

	<b>Total</b>	<b>Less than One Year</b>	<b>One-Three Years</b>	<b>Three-Five Years</b>	<b>Thereafter</b>
Operating leases	\$ 69,157	\$ 18,446	\$ 33,488	\$ 7,532	\$ 9,691
Total debt	4,812,094	105,378	496,153	1,080,889	3,129,674
Scheduled interest payments	2,104,779	368,344	1,045,701	595,351	95,383
Preferred stock dividends	401,106	139,035	262,071		
Revolving credit facility	300,000	300,000			
	\$ 7,687,136	\$ 931,203	\$ 1,837,413	\$ 1,683,772	\$ 3,234,748

The chart above does not include (i) short-term borrowings held by Matrix in the amount of approximately \$144.4 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, 2007, the Company is unable to make reasonably reliable estimates of the period of cash settlement with the respective taxing authority. Therefore, \$77.6 million of unrecognized tax benefits have been excluded from the contractual obligations table above. See Note 11 to the Consolidated Financial Statements for a discussion on income taxes.

## **Table of Contents**

We lease certain real 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. We have also entered into agreements to lease vehicles, which are typically 24 to 36 months, for use by our key employees.

Total debt consists of the U.S. Tranche A Term Loans of \$312.5 million, the Euro Tranche A Term Loans of \$350.4 (\$516.1) million, the U.S. Tranche B Term Loans of \$2.56 billion, the Euro Tranche B Term Loans of \$525.0 (\$773.3) million, a Revolving Facility of \$300.0 million, and \$600.0 million in convertible notes. Additionally, with the acquisition of Matrix, Mylan assumed debt which consists of a term loan of \$24.5 (\$36.1) million.

Matrix's borrowings consisted primarily of two Euro-denominated Facilities ( Facility A and Facility B ). On July 5, 2007, Facility A was repaid in the amount of \$82.5 (\$121.5) million. Matrix's effective interest rate for Facility B was EURIBO plus 129 basis points, or 5.861% at December 31, 2007. Facility B is payable over three years in semi-annual installments beginning in October 2007. On September 30, 2007, Matrix paid \$50.0 (\$73.6) million on Facility B reducing the principal amount of the loan to \$32.5 (\$47.9) million. Then on October 5, 2007, in accordance with the terms of Facility B, Matrix paid \$8.0 (\$11.8) million reducing the principal amount of the loan to \$24.5 (\$36.1) million.

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 Revolving Facility, the Convertible Notes, and Matrix debt. Variable debt interest payments are estimated using current interest rates, as discussed above.

In addition to the above, the Company has entered into various product licensing and development agreements. In some of these arrangements, we provide funding for the development of the product or obtain the rights to the use of the patent, through milestone payments, in exchange for marketing and distribution rights to the product. Because milestones represent the completion of specific contractual events and it is uncertain if and when these milestones will be achieved, such contingencies have not been recorded on the Company's Consolidated Balance Sheet.

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.

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

At December 31, 2007, the Company has \$172.9 million in letters of credit outstanding.

## **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 of the 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, goodwill and the impact of existing legal matters.

**Table of Contents***Net Revenue Provisions*

Net revenues are recognized for product sales upon shipment 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 to net revenues and accounts receivable and within other current liabilities. Accounts receivable are presented net of allowances relating to these provisions, which were \$487.0 million and \$404.7 million at December 31, 2007 and March 31, 2007, respectively. Other current liabilities include \$149.7 million and \$51.9 million at December 31, 2007 and March 31, 2007, respectively, 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 the nine months ended December 31, 2007:

	<b>Balance at 3/31/2007</b>	<b>Balances Acquired through the Acquisition of Merck Generics</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 12/31/2007</b>
<i>(In thousands)</i>						
Chargebacks	\$ 208,962	\$ 9,620	\$ (1,029,169)	\$ 1,012,799	\$ (342)	\$ 201,870
Customer performance and promotions	\$ 73,222	\$ 65,550	\$ (219,528)	\$ 199,705	\$ 398	\$ 119,348
Returns	\$ 49,576	\$ 34,212	\$ (35,774)	\$ 38,328	\$ 57	\$ 86,399

The accrual for chargebacks decreased as a result of numerous factors including the timing of the issuance of credits and a decrease made to the wholesale acquisition cost of several products, off of which chargebacks are calculated. The accrual for customer performance and promotions includes direct rebates as well as promotional programs. The accrual decreased primarily due to the timing of the issuance of direct rebate credits. The increase to the accrual for product returns is due to the acquisition of Merck Generics in the current year.

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 relationship 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, 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.

*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 in the market of additional generic competition, changes in formularies or launch of

**Table of Contents**

over-the-counter products, to name a few, 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.

*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.

*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, is 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 are 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 purchase price allocation for the acquisition of Merck Generics is preliminary and is based on the information that was available as of the acquisition date to estimate the fair value of assets acquired and liabilities assumed. Management believes that information provides a reasonable basis for allocating the purchase price, but the Company is awaiting additional information necessary to finalize the purchase price allocation. The fair values reflected in the purchase price allocation may be adjusted upon the final valuation, and such adjustments could be significant. The Company expects to finalize the valuation and complete the purchase price allocation as soon as possible but no later than one year from the acquisition date.

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. As a result of our acquisition of Merck

Generics, we recorded on our balance sheet goodwill of \$3.17 billion and \$2.65 billion of intangible assets.



## **Table of Contents**

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 annual tax rate 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 annual tax rate 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 annual tax rate includes the impact of reserve provisions and changes to reserves. Favorable resolution would be recognized as a reduction to the Company's annual tax rate in the year of resolution. The Company's tax reserves are presented in the balance sheet principally within accrued income taxes.

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.

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 impact on the Company's financial position or results of operations, such estimates are considered to be critical accounting estimates.

## **Recent Accounting Pronouncements**

In December 2007, the Financial Accounting Standards Board (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

**Table of Contents**

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. The Company is currently evaluating the potential impact of adopting SFAS No. 160 on its Consolidated Financial Statements.

In December 2007, the FASB issued SFAS No. 141(R), *Business Combinations*, (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 of 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 September 2006, the FASB issued SFAS No. 157, *Fair Value Measurements*, (SFAS No. 157). SFAS No. 157 defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles, and expands disclosures about fair value measurements. The provisions of this standard apply to other accounting pronouncements that require or permit fair value measurements. SFAS No. 157, as it relates to financial assets and financial liabilities, became effective January 1, 2008. On February 12, 2008, the FASB issued FSP No. FAS 157-2, *Effective Date of FASB Statement No. 157*, which delays the effective date of SFAS No. 157 for all nonfinancial assets and nonfinancial liabilities, except those that are recognized or disclosed at fair value in the financial statements on at least an annual basis, until January 1, 2009 for calendar year-end entities. Upon adoption, the provisions of SFAS No. 157 are to be applied prospectively with limited exceptions. The Company is currently evaluating the impact of adopting SFAS No. 157 on its Consolidated Financial Statements.

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities* ( SFAS No. 159 ), providing companies with an option to report selected financial assets and liabilities at fair value. This statement is effective for fiscal years beginning after November 15, 2007. The Company does not expect to elect the fair value option for any of its assets or liabilities.

In June 2007, the FASB ratified EITF Issue No. 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities* (EITF 07-3). EITF 07-3 requires non-refundable advance payments for goods and services to be used in future research and development (R&D) activities to be recorded as assets and the payments to be expensed when the R&D activities are performed. EITF 07-3 applies prospectively for new contractual arrangements entered into beginning in the first quarter of fiscal year 2008. Prior to adoption, we recognized these non-refundable advance payments as an expense upon payment. Management is currently assessing the impact of adopting EITF 07-3 on its Consolidated Financial Statements.

In August 2007, the FASB issued an exposure draft of a proposed FASB Staff Position ( FSP ) reflecting new rules that would change the accounting treatment for certain convertible debt instruments, including our Senior Convertible Notes. Under the proposed new rules for convertible debt instruments 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 proposed new rules for the debentures is that

the equity component would be included in the paid-in-capital section of stockholders' equity on our 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. Higher interest expense would result by recognizing accretion of the discounted carrying value of the Senior Convertible Notes to their face amount as interest expense over the term of the Senior Convertible Notes. The Company is currently evaluating the proposed

**Table of Contents**

new rules and the impact of adopting this Proposed FSP, if it should be adopted. However, if the FSP is issued as proposed then, upon adoption, we expect to have higher interest expense starting in 2008 due to the interest expense accretion, and prior period interest expense associated with the Senior Convertible Notes would also reflect higher than previously reported interest expense due to retrospective application.

**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 Merck Generics, our exposure to these areas was materially increased. We now manage 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 Merck Generics, we incurred substantial indebtedness which has variable interest rates (see *Liquidity and Capital Resources*) and are subject to increased foreign currency exchange rate risk.

*Foreign Exchange Risk*

A significant portion of our revenues and earnings is exposed to changes in foreign exchange rates. We seek to manage our 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. Our 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, we protect against possible declines in the reported net assets of our Euro functional-currency subsidiaries through the use of Euro denominated debt.

In conjunction with the Matrix transaction, 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 transaction. In conjunction with the acquisition of Merck Generics, 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, *Accounting for Derivative Instruments and Hedging Activities* ( 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.

Our 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 exchange rates of 10%, the expected net effect on net income related to our foreign currency denominated financial instruments would be immaterial. For additional details, see Notes to Consolidated Financial Statements *Note 9. Financial Instruments and Risk Management*.

*Interest Rate Risk*

Our exposure to interest rate risk arises primarily from our U.S. dollar and Euro borrowings. We are also subject to interest rate risk on U.S. Dollar and Euro investments. We invest and borrow primarily on a variable-rate

## **Table of Contents**

basis. From time to time, depending on market conditions, we will fix interest rates on borrowings through the use of derivative financial instruments such as interest rate swaps.

Our borrowings consist principally of \$3.2 billion in U.S. dollar denominated loans and \$1.3 billion in Euro denominated debt under our Senior Credit Agreement and \$600.0 million in Senior Convertible Notes. For additional details, see Notes to Consolidated Financial Statements *Note 10. Long-Term Debt*.

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 Convertible Notes will fluctuate as the market value of our common stock fluctuates. As of December 31, 2007, the fair value of our Convertible Notes was approximately \$545.5 million. The fair value of our Term Loan facility was approximately 99% of the carrying value. 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 \$30.0 million per year.

Our investments are comprised of available for sale securities, overnight deposits, market auction securities and money market funds. The primary objectives for the available for sale debt 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. Substantially all our investments have a duration of less than three months, creating minimal exposure to fluctuations in market values.

### *Available for Sale Securities*

In addition to available for sale securities, investments are made in overnight deposits, 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, 2007 or March 31, 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, 2007, the Company had invested \$88.9 million in available for sale securities, of which \$7.0 million will mature within one year and \$81.9 million will mature after one year. The short duration to maturity creates minimal exposure to fluctuations in fair values for investment that will mature within one year. However, a significant change in current interest rates could affect the fair value of the remaining \$81.9 million of available for sale securities that mature after one year. A 5% adverse change in interest rates on available for sale securities that mature after one year would result in a \$4.1 million decrease in the available for sale securities.

### *Long-Term Debt*

On March 1, 2007, Mylan entered into a Purchase Agreement (the *Convertible Notes 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 *Convertible Notes*). The 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 Convertible Notes will mature on March 15, 2012, subject to earlier repurchase or conversion. The 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.

As of December 31, 2007, the fair value of our Convertible Notes was approximately \$545.5 million.





**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, 2007 and March 31, 2007</u>	66
<u>Consolidated Statements of Operations for the Nine Months Ended December 31, 2007, and Fiscal Years Ended March 31, 2007 and 2006</u>	67
<u>Consolidated Statements of Shareholders' Equity for the Nine Months Ended December 31, 2007, and Fiscal Years Ended March 31, 2007 and 2006</u>	68
<u>Consolidated Statements of Cash Flows for the Nine Months Ended December 31, 2007, and Fiscal Years Ended March 31, 2007 and 2006</u>	70
<u>Notes to Consolidated Financial Statements</u>	71
<u>Management's Report on Internal Control over Financial Reporting</u>	106
<u>Reports of Independent Registered Public Accounting Firm</u>	107
<u>Supplementary Financial Information</u>	110

**Table of Contents**

**Mylan Inc.**  
**Consolidated Balance Sheets**  
(in thousands, except share and per share amounts)

	<b>December 31, 2007</b>	<b>March 31, 2007</b>
Assets		
Current assets:		
Cash and cash equivalents	\$ 484,202	\$ 1,252,365
Available for sale securities	91,361	174,207
Accounts receivable, net	1,132,121	350,294
Inventories	1,063,840	429,111
Deferred income tax benefit	192,113	145,343
Prepaid expenses and other current assets	95,664	60,724
Total current assets	3,059,301	2,412,044
Property, plant and equipment, net	1,102,932	686,739
Intangible assets, net	2,978,706	352,780
Goodwill	3,855,971	612,742
Deferred income tax benefit	18,703	45,779
Other assets	337,563	143,783
Total assets	\$ 11,353,176	\$ 4,253,867
Liabilities and shareholders' equity		
Liabilities		
Current liabilities:		
Trade accounts payable	\$ 643,873	\$ 160,286
Short-term borrowings	144,355	108,259
Income taxes payable	133,715	78,387
Current portion of long-term debt and other long-term obligations	410,934	124,782
Other current liabilities	669,474	228,821
Total current liabilities	2,002,351	700,535
Deferred revenue	122,870	90,673
Long-term debt	4,706,716	1,654,932
Other long-term obligations	206,672	29,760
Deferred income tax liability	876,816	85,900
Total liabilities	7,915,425	2,561,800
Minority interest	34,325	43,207
Shareholders' equity		
Preferred stock - par value \$0.50 per share		
Shares authorized: 5,000,000 as of December 31, 2007 and March 31, 2007, respectively	1,070	

Edgar Filing: MYLAN INC. - Form 10-KT/A

Shares issued: 2,139,000 and 0 as of December 31, 2007 and March 31, 2007, respectively

Common stock par value \$0.50 per share

Shares authorized: 600,000,000 as of December 31, 2007 and March 31, 2007, respectively

Shares issued: 395,260,355 and 339,361,201 as of December 31, 2007 and March 31, 2007, respectively

Additional paid-in capital

Retained earnings

Accumulated other comprehensive earnings

Less treasury stock at cost

Shares: 90,885,188 and 90,948,957 as of December 31, 2007 and March 31, 2007, respectively

Total shareholders equity

Total liabilities and shareholders equity

197,630	169,681
3,785,729	962,746
922,857	2,103,282
83,044	1,544
4,990,330	3,237,253
1,586,904	1,588,393
3,403,426	1,648,860
\$ 11,353,176	\$ 4,253,867

*See Notes to Consolidated Financial Statements*

**Table of Contents**

**Mylan Inc.**  
**Consolidated Statements of Operations**  
(in thousands, except per share amounts)

	<b>Nine Months Ended December 31, 2007</b>	<b>Fiscal Year Ended March 31, 2007                      2006</b>	
Revenues			
Net revenues	\$ 2,162,943	\$ 1,586,947	\$ 1,240,011
Other revenues	15,818	24,872	17,153
<b>Total revenues</b>	<b>2,178,761</b>	<b>1,611,819</b>	<b>1,257,164</b>
Cost of sales	1,304,313	768,151	629,548
<b>Gross profit</b>	<b>874,448</b>	<b>843,668</b>	<b>627,616</b>
Operating expenses:			
Research and development	146,063	103,692	102,431
Acquired in-process research and development	1,269,036	147,000	
Selling, general and administrative	449,598	215,538	225,380
Litigation settlements, net	(1,984)	(50,116)	12,417
<b>Total operating expenses</b>	<b>1,862,713</b>	<b>416,114</b>	<b>340,228</b>
(Loss) earnings from operations	(988,265)	427,554	287,388
Interest expense	179,410	52,276	31,285
Other income, net	86,611	50,234	18,502
(Loss) earnings before income taxes and minority interest	(1,081,064)	425,512	274,605
Provision for income taxes	60,073	208,017	90,063
(Loss) earnings before minority interest	(1,141,137)	217,495	184,542
Minority Interest	(3,112)	211	
Net (loss) earnings before preferred dividends	(1,138,025)	217,284	184,542
Preferred dividends	15,999		
Net (loss) earnings available to common shareholders	\$ (1,154,024)	\$ 217,284	\$ 184,542
Earnings per common share:			
Basic	\$ (4.49)	\$ 1.01	\$ 0.80
Diluted	\$ (4.49)	\$ 0.99	\$ 0.79
Weighted average common shares outstanding:			
Basic	257,150	215,096	229,389

Diluted	257,150	219,120	234,209
---------	---------	---------	---------

*See Notes to Consolidated Financial Statements*

**Table of Contents**

**Mylan Inc.**  
**Consolidated Statements of Shareholders Equity**  
(in thousands, except share and per share amounts)

	<b>Nine Months Ended December 31, 2007</b>	<b>Fiscal Year Ended March 31, 2007                      2006</b>	
Preferred stock shares issued:			
Shares at beginning of year			
Issuance of preferred stock	2,139,000		
Shares at end of year	2,139,000		
Common stock shares issued:			
Shares at beginning of year	339,361,201	309,150,251	304,434,724
Issuance of common stock	55,440,000	26,162,500	
Stock options exercised, net of shares tendered for payment	459,154	4,048,450	4,715,527
Shares at end of year	395,260,355	339,361,201	309,150,251
Treasury stock:			
Shares at beginning of year	(90,948,957)	(98,971,431)	(35,129,643)
Issuance of restricted stock, net of shares withheld	63,769	(35,665)	35,463
Shares issued for the acquisition of Matrix		8,058,139	
Stock purchases			(63,877,251)
Shares at end of year	(90,885,188)	(90,948,957)	(98,971,431)
Common shares outstanding	304,375,167	248,412,244	210,178,820
Preferred stock, \$0.50 par:			
Balance at beginning of year	\$	\$	\$
Issuance of preferred stock, net	1,070		
Balance at end of year	1,070		
Common stock, \$0.50 par:			
Balance at beginning of year	169,681	154,575	152,217
Issuance of common stock, net	27,720	13,081	
Stock options exercised	229	2,025	2,358
Balance at end of year	197,630	169,681	154,575
Additional paid-in capital:			
Balance at beginning of year	962,746	418,954	354,172

Edgar Filing: MYLAN INC. - Form 10-KT/A

Issuance of common stock, net	720,331	476,015	
Issuance of preferred stock, net	2,072,816		
Sale of warrants		45,360	
Shares issued for the acquisition of Matrix		23,045	
Purchase of bond hedge, net of tax of \$44,100		(81,900)	
Stock options exercised	7,503	47,242	54,531
Issuance of restricted stock, net of shares withheld	(1,485)	(2,526)	181
Unearned compensation			3,142
Stock-based compensation expense	17,332	22,156	
Tax benefit of stock option plans	5,648	14,419	7,221
Other	838	(19)	(293)
Balance at end of year	3,785,729	962,746	418,954
Retained earnings:			
Balance at beginning of year	2,103,282	1,939,045	1,808,802
Net earnings	(1,138,025)	217,284	184,542
Adoption of FIN 48, net of tax	(11,478)		
Dividends on preferred shares	(15,999)		
Dividends declared (\$0.06 per share for the nine months ended December 31, 2007 and \$0.24 per share for fiscal year ended 2007 and 2006)	(14,923)	(53,047)	(54,299)
Balance at end of year	922,857	2,103,282	1,939,045

*See Notes to Consolidated Financial Statements*

**Table of Contents**

**Mylan Inc.**  
**Consolidated Statements of Shareholders Equity (continued)**

(in thousands, except share and per share amounts)

	<b>Nine Months Ended December 31, 2007</b>	<b>Fiscal Year Ended March 31, 2007</b>	<b>2006</b>
Accumulated other comprehensive earnings:			
Balance at beginning of year	1,544	2,450	870
Adjustment to initially adopt SFAS No. 158, net of tax of \$751		(1,272)	
Change in unrecognized losses and prior service cost related to post-retirement plans, net of tax	(663)		
Foreign currency translation adjustment	87,602	1,266	
Net unrecognized losses on derivatives, net of tax	(4,723)		
Net unrealized (loss) gain on marketable securities, net of tax	(716)	(900)	1,580
Balance at end of year	83,044	1,544	2,450
Treasury stock, at cost:			
Balance at beginning of year	(1,588,393)	(1,727,373)	(470,125)
Issuance of restricted stock, net of shares withheld	1,489	(1,716)	619
Shares issued for the acquisition of Matrix		140,696	
Stock purchases			(1,257,867)
Balance at end of year	(1,586,904)	(1,588,393)	(1,727,373)
Total shareholders equity	\$ 3,403,426	\$ 1,648,860	\$ 787,651
Comprehensive (loss) earnings:			
Net (loss) earnings	\$ (1,138,025)	\$ 217,284	\$ 184,542
Other comprehensive (loss) earnings, net of tax:			
Net unrealized holding gains (losses) gains on securities, net of tax	(525)	(1,569)	1,397
Reclassification for (gains) losses included in net earnings	(191)	669	183
Net unrecognized losses on derivatives, net of tax	(4,723)		
Change in unrecognized losses and prior service cost related to post-retirement plans, net of tax	(663)		
Foreign currency translation adjustment	87,602	1,266	
Other comprehensive earning, net of tax	81,500	366	1,580
Total comprehensive (loss) earnings	\$ (1,056,525)	\$ 217,650	\$ 186,122



*See Notes to Consolidated Financial Statements*

**Table of Contents**

**Mylan Inc.**  
**Consolidated Statements of Cash Flows**  
(in thousands)

	<b>Nine Months Ended December 31, 2007</b>	<b>Fiscal Year Ended March 31, 2007</b>	<b>2006</b>
Cash flows from operating activities:			
Net (loss) earnings	\$ (1,138,025)	\$ 217,284	\$ 184,542
Adjustments to reconcile net earnings to net cash provided from operating activities:			
Depreciation and amortization	157,800	61,512	46,827
Stock-based compensation expense	17,332	22,156	
Minority interest	(3,112)	211	
In-process research and development	1,269,036	147,000	
Net (income) loss from equity method investees	(2,573)	(6,659)	2,538
Gain of foreign exchange contracts	(85,063)		
Change in estimated sales allowances	31,337	14,386	41,047
Restructuring provision			20,921
Deferred income tax benefit	(77,131)	(50,479)	(23,635)
Other non-cash items	54,408	7,914	15,768
Litigation settlements, net	(4,526)	6,464	14,108
Cash received from Somerset		5,870	
Changes in operating assets and liabilities:			
Accounts receivable	(124,385)	(60,773)	19,081
Inventories	16,305	(28,987)	6,012
Trade accounts payable	86,467	(29,312)	20,534
Income taxes	(34,632)	73,567	(23,821)
Deferred revenue	34,864	(5,504)	106,642
Other operating assets and liabilities, net	(30,413)	15,542	(14,003)
Net cash provided by operating activities	167,689	390,192	416,561
Cash flows from investing activities:			
Capital expenditures	(110,538)	(161,851)	(103,689)
Acquisitions, net of cash acquired	(7,001,930)	(761,049)	
Purchase of available for sale securities	(275,802)	(655,948)	(686,569)
Proceeds from sale of available for sale securities	357,922	848,520	991,060
Other items, net	(4,976)	(407)	(5,710)
Net cash (used in) provided by investing activities	(7,035,324)	(730,735)	195,092
Cash flows from financing activities:			
Cash dividends paid	(29,825)	(50,751)	(49,772)
Payment of financing fees	(89,538)	(15,329)	(14,662)
Proceeds from the issuance of preferred stock, net	2,073,886		
Change in short-term borrowing, net	26,240		

Edgar Filing: MYLAN INC. - Form 10-KT/A

Excess tax benefit from stock-based compensation	2,171	4,158	
Proceeds from issuance of common stock, net	748,051	657,678	
Purchase of bond hedge		(126,000)	
Proceeds from issuance of warrants		45,360	
Proceeds from issuance of long-term debt	7,701,240	1,556,251	775,000
Payment of long-term debt	(4,389,183)	(689,938)	(87,062)
Purchase of common stock			(1,257,867)
Proceeds from exercise of stock options	7,732	49,824	56,889
Change in outstanding checks in excess of cash disbursements accounts	18,008	10,403	(21,788)
Other items, net		1,160	
Net cash provided by (used in) financing activities	6,068,782	1,442,816	(599,262)
Effect on cash of changes in exchange rates	30,690	(32)	
Net (decrease) increase in cash and cash equivalents	(768,163)	1,102,241	12,391
Cash and cash equivalents beginning of year	1,252,365	150,124	137,733
Cash and cash equivalents end of year	\$ 484,202	\$ 1,252,365	\$ 150,124
Supplemental disclosures of cash flow information:			
Cash paid during the year for:			
Income taxes	\$ 179,092	\$ 176,353	\$ 137,519
Interest	\$ 174,034	\$ 59,996	\$ 29,110

*See Notes to Consolidated Financial Statements*

**Table of Contents****Mylan Inc.****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, 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 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 United States (U.S.) and the European Union (EU) at market formation. Matrix also has investments in companies in Europe, China, South Africa and India. 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. As a result, this Form 10-K is a transition report and includes financial information for the period from April 1, 2007 through December 31, 2007 (the Transition Period). Subsequent to this report, our reports on Form 10-K will cover the calendar year January 1 to December 31. We will refer to the period beginning April 1, 2006 through March 31, 2007 as fiscal 2007 and the period beginning April 1, 2005 through March 31, 2006 as fiscal 2006.

**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 the generics business (Merck Generics) of Merck KGaA. Accordingly, Mylan began consolidating the results of operations of Merck Generics as of October 2, 2007. See Note 3 for additional information. As discussed above, Mylan now has three reportable segments, the Generics Segment, the Matrix Segment and the Specialty Segment. Mylan previously reported as two segments. In accordance with Statement of Financial Accounting Standards (SFAS) No. 131, *Disclosures about Segments of an Enterprise and Related Information*, segment information for earlier periods has been recast.

**Cash and Cash Equivalents.** Cash and cash equivalents are composed of highly liquid investments with an original maturity of three months or less at the date of purchase. The Company utilizes a cash management system under which a book cash overdraft in the amount of \$0 and \$18.0 million at December 31, 2007 and March 31, 2007, respectively, exists for the Company's primary disbursement accounts. This overdraft, which is included in accounts payable, represents uncleared checks in excess of the cash balance in the bank account at the end of the reporting period. The Company transfers cash on an as-needed basis to fund clearing checks.

**Available for Sale Securities.** Debt and marketable equity securities are classified as available-for-sale and are recorded at fair value based on quoted market prices, 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 securities available-for-sale are computed on a specific security basis and are included in other income.

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

**Table of Contents**

Mylan invests its excess cash in high-quality, liquid money market instruments (principally commercial paper, government, municipal and government agency notes and bills) maintained by financial institutions. The Company maintains deposit balances at certain of these financial institutions in excess of federally insured amounts.

Mylan performs ongoing credit evaluations of its customers and generally does not require collateral. Approximately 34% and 51% of the accounts receivable balances represent amounts due from three customers at December 31, 2007 and March 31, 2007, respectively. Total allowances for doubtful accounts were \$47.7 million and \$15.1 million at December 31, 2007 and March 31, 2007, respectively.

***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 \$57.1 million, \$39.1 million and \$32.1 million for the nine months ended December 31, 2007 and fiscal years 2007 and 2006, 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 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. 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 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 we have 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.

**Table of Contents**

***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 the Company 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%.

***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 nine months ended December 31, 2007. The following briefly describes the nature of each provision and how such provisions are estimated.

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 believes that it was able to reasonably estimate the amount of potential price adjustments. Accordingly, all revenues on shipments previously deferred have been recognized and revenue is currently being recorded as described above.

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 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.

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 nine months ended December 31, 2007 and fiscal year ended March 31, 2007. Such allowances were \$487.0 million and \$404.7 million at December 31, 2007

**Table of Contents**

and March 31, 2007, respectively. Other current liabilities include \$149.7 million and \$51.9 million at December 31, 2007 and March 31, 2007, respectively, 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.

The Company recognizes all non-refundable payments as revenue in accordance with the guidance provided in the ( SEC ) Staff Accounting Bulletin ( SAB ) No. 104, *Revenue Recognition, corrected copy ( SAB No. 104 )*, 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 a 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 Statement 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, collectibility is reasonably assured, the sales price is fixed or determinable and there is persuasive evidence of an arrangement.

Two of the Company's customers accounted for 11% and 16%, of consolidated net revenues during the nine months ended December 31, 2007. Three customers accounted for 13%, 18% and 19%, respectively, of net revenues in fiscal 2007, and three customers accounted for 16%, 14% and 17%, respectively, of net revenues in fiscal 2006.

***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 we have 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. See Note 11 for the Company's adoption of FIN 48, effective April 1, 2007.

***(Loss) Earnings per Common Share.*** Basic (loss) earnings per share excludes dilution and is computed by dividing net (loss) earnings available to common stockholders 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 if the impact is dilutive.

On November 19, 2007, the Company issued 2,139,000 shares of 6.50% mandatory convertible preferred stock. This preferred stock is convertible into between a total of 125,234,172 shares and 152,785,775 shares of our common stock, subject to anti-dilution adjustments, depending on the average market price of our common stock over the 20 trading-day period ending on the third trading day prior to conversion.

**Table of Contents**

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

	<b>Nine Months Ended</b>		<b>Fiscal Year Ended</b>	
	<b>December 31, 2007</b>		<b>March 31, 2007      2006</b>	
<i>(in thousands, except share and per share amounts)</i>				
<b>Basic and diluted (loss) earnings available to common shareholders (numerator):</b>				
Net (loss) earnings	\$	(1,138,025)	\$ 217,284	\$ 184,542
Preferred stock dividends		15,999		
Net (loss) earnings available to common shareholders	\$	(1,154,024)	\$ 217,284	\$ 184,542
<b>Shares (denominator):</b>				
Weighted average shares outstanding		257,150	215,096	229,389
<b>Dilutive securities:</b>				
Stock-based awards			4,024	4,820
Preferred stock				
Total dilutive shares outstanding assuming conversion		257,150	219,120	234,209
<b>(Loss) earnings per common share:</b>				
Basic	\$	(4.49)	\$ 1.01	\$ 0.80
Diluted	\$	(4.49)	\$ 0.99	\$ 0.79

Additional stock options representing 12,465,457, 1,562,645, and 312,750 shares of common stock were outstanding as of December 31, 2007, and fiscal years ended March 31, 2007 and 2006, respectively, but were not included in the computation of diluted earnings per share because the effect would be anti-dilutive. In addition, the Company considered the effect on diluted earnings per share if the preferred stock conversion feature would have been exercised at December 31, 2007. However, the preferred stock conversion would have been anti-dilutive and as such was not included in the computation of diluted earnings per share.

**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 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 ).

Mylan adopted the provisions of SFAS No. 123R, using the modified prospective transition method. Under this method, compensation expense recognized in 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. Results for prior periods have not been restated.



**Table of Contents**

The previously disclosed pro forma effects of recognizing the estimated fair value of stock-based employee compensation for fiscal year ended March 31, 2006 were as follows:

<b>Fiscal Year Ended March 31,</b> <i>(in thousands, except per share amounts)</i>	<b>2006</b>
Net earnings, as reported	\$ 184,542
Add: Stock-based compensation expense included in reported net earnings, net of related tax effects	2,649
Deduct: Total compensation expense determined under fair-value based method for all stock awards, net of related tax effects	(11,845)
Pro forma net earnings	\$ 175,346
Earnings per share:	
Basic as reported	\$ 0.80
Basic pro forma	\$ 0.76
Diluted as reported	\$ 0.79
Diluted pro forma	\$ 0.75

**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 exchange rates are recorded in the statement of operations.

**Derivatives.** From time to time the Company may enter into derivative instruments (mainly foreign exchange forward contracts and purchased currency options and interest rate swaps) 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 and to hedge the variability in interest expense on floating rate debt. When such instruments qualify for hedge accounting under SFAS No. 133, *Accounting for Derivative Instruments and Hedging Activities*, they are recognized on the balance sheet with the change in the fair value recorded as a component of other comprehensive income. 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 currency and interest rate exposures, which exist as part of ongoing business operations. The Company carries derivative instruments on the balance sheet at fair value, determined by reference to market data such as forward rates for currencies 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, 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.

**Table of Contents**

***Recent Accounting Pronouncements.*** In December 2007, the Financial Accounting Standards Board ( 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 statement of financial position 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 income; 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. The Company is currently evaluating the potential impact of adopting SFAS No. 160 on its consolidated financial statements.

In December 2007, the FASB issued SFAS No. 141(R), *Business Combinations*, (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 as of 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 February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities* ( SFAS No. 159 ), providing companies with an option to report selected financial assets and liabilities at fair value. This statement is effective for fiscal years beginning after November 15, 2007. The Company does not expect to elect the fair value option for any of its assets or liabilities.

In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurements*, (SFAS No. 157). SFAS No. 157 defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles, and expands disclosures about fair value measurements. The provisions of this standard apply to other accounting pronouncements that require or permit fair value measurements. SFAS No. 157, as it relates to financial assets and financial liabilities, became effective January 1, 2008. On February 12, 2008, the FASB issued FSP No. FAS 157-2, *Effective Date of FASB Statement No. 157*, which delays the effective date of SFAS No. 157 for all nonfinancial assets and nonfinancial liabilities, except those that are recognized or disclosed at fair value in the financial statements on at least an annual basis, until January 1, 2009 for calendar year-end entities. Upon adoption, the provisions of SFAS No. 157 are to be applied prospectively with limited exceptions. The Company is currently evaluating the impact of adopting SFAS No. 157 on its consolidated financial statements.

In August 2007, the FASB issued an exposure draft of a proposed FASB Staff Position ( FSP ) reflecting new rules that would change the accounting treatment for certain convertible debt instruments, including our Senior Convertible Notes. Under the proposed new rules for convertible debt instruments 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 proposed new rules for the debentures is that the equity component would be included in the paid-in-capital section of stockholders' equity on our 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. Higher interest expense would result by recognizing accretion of the discounted carrying value of the Senior Convertible Notes to their face amount as interest expense over the term of the Senior Convertible Notes. The Company is currently evaluating the proposed new rules and the impact of adopting this Proposed FSP, if it should be adopted. However, if the FSP is issued as



**Table of Contents**

proposed then, upon adoption, we expect to have higher interest expense starting in 2008 due to the interest expense accretion, and prior period interest expense associated with the Senior Convertible Notes would also reflect higher than previously reported interest expense due to retrospective application.

In June 2007, the FASB ratified EITF Issue No. 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities* (EITF 07-3). EITF 07-3 requires non-refundable advance payments for goods and services to be used in future research and development (R&D) activities to be recorded as assets and the payments to be expensed when the R&D activities are performed. EITF 07-3 applies prospectively for new contractual arrangements entered into beginning in the first quarter of fiscal year 2008. Prior to adoption, the Company recognized these non-refundable advance payments as an expense upon payment. Management is currently assessing the impact of adopting EITF 07-3 on its Consolidated Financial Statements.

**Note 3. Acquisitions***Acquisition of Merck Generics*

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 Merck Generics and paid a purchase price of approximately \$7.0 billion.

In accordance with SFAS No. 141, *Business Combinations* ( SFAS 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 from Merck Generics were recorded at the date of acquisition, at the preliminary estimate of their respective fair values. The purchase price plus acquisition costs exceeded the preliminary estimate of fair values of acquired assets and assumed liabilities. This resulted in the recognition of goodwill in the 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 Merck Generics from October 2, 2007 to December 31, 2007 are included in the consolidated financial statements. The allocation of assets acquired and liabilities assumed for Merck Generics 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.

**Table of Contents**

- (2) Included in non-current assets is \$137.1 million of receivables for the agreement of Merck KGaA under the terms of the acquisition to indemnify Mylan for certain acquired significant litigation and tax liabilities (see Note 17).
- (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 Merck Generics employees and costs to exit certain activities of Merck Generics and were recorded as a liability in conjunction with recording the initial purchase price. At December 31, 2007, the plans related to these exit activities have not been finalized. There may still be additional exit costs incurred.
- (4) Included in property, plant and equipment are \$36.4 million of asset writedowns that have impacted goodwill. These costs relate to adjusting equipment and buildings down to their expected residual value upon their sale or closure.

The purchase price allocation is preliminary, including the allocation of goodwill, and is based on the information that was available as of the acquisition date to estimate the fair value of assets acquired and liabilities assumed. Management believes that the information provides a reasonable basis for allocating the purchase price but the Company is awaiting additional information necessary to finalize the purchase price allocation. The fair values reflected above may be adjusted upon the final valuation and such adjustments could be significant. The Company expects to finalize the valuation and complete the purchase price allocation as soon as possible but no later than one year from the acquisition date.

At December 31, 2007, as a result of our preliminary allocation of goodwill, approximately \$2.4 billion and \$711.2 million were allocated to our Generics Segment and Specialty Segments, respectively.

In conjunction with the acquisition of Merck Generics, 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), for the nine month periods 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 Merck Generics, 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 based 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

**Table of Contents**

approximately 51.5% of Matrix's outstanding shares from certain 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 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 total 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 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.

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 transaction. The Company accounted for this instrument under the provisions of SFAS No. 133. This instrument did not qualify for hedge accounting treatment under SFAS 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 12 month period 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.

**Table of Contents***Pro forma financial results*

The operating results of Merck Generics 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 the Merck Generics acquisition occurred on April 1, 2007. Matrix's actual results of operations are included in 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 Merck Generics 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 Merck Generics. 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 Merck Generics. 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 10 and 12).

	<b>Nine Months Ended December 31, 2007 Unaudited</b>	<b>Fiscal Year Ended March 31, 2007 Unaudited</b>
<i>(in thousands, except per share data)</i>		
Total revenues	\$ 3,428,231	\$ 4,197,786
Net (loss) earnings before preferred dividend	(1,290,242)	(1,311,466)
Preferred dividend	(104,276)	(121,656)
Net (loss) earnings available to common shareholders	\$ (1,394,518)	\$ (1,433,122)
Earnings 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

**Note 4. Restructuring**

On June 14, 2005, the Company announced that it was closing its branded subsidiary, Mylan Bertek, and transferring the responsibility for marketing Mylan Bertek's products to other Mylan subsidiaries. In conjunction with this

restructuring, the Company incurred restructuring charges of \$20.9 million, pre-tax, during the year ended March 31, 2006. Of this, \$1.0 million is included in research and development expense, with the remainder in selling, general and administrative expense. Of the \$20.9 million charge, \$15.1 million was related to employee termination and severance costs primarily with respect to the involuntary termination of the Mylan Bertek sales force and represented cash termination payments paid to the affected employees as a direct result of the restructuring. The remainder consisted of non-cash asset write-downs of \$1.6 million and exit costs of \$4.2 million, primarily lease termination costs. As of March 31, 2006, the Company's restructuring was substantially complete.

In connection with the acquisition of Merck Generics, the Company included \$74.3 million of (restructuring liabilities) in the purchase price allocation, however, no material payments have been made during the nine months ended December 31, 2007.



**Table of Contents****Note 5. 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 31 to December 31. 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 consolidated financial statements.

**Mylan Inc.****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	(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-KT/A

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 6. Balance Sheet Components**

Selected balance sheet components consisted of the following:

<i>(in thousands)</i>	<b>December 31, 2007</b>	<b>March 31, 2007</b>
Inventories:		
Raw materials	\$ 255,744	\$ 148,109
Work in process	160,918	95,655
Finished goods	647,178	185,347
	\$ 1,063,840	\$ 429,111
Property, plant and equipment:		
Land and improvements	\$ 62,824	\$ 29,850
Buildings and improvements	583,097	297,505
Machinery and equipment	980,340	471,990
Construction in progress	125,682	141,301
	1,751,943	940,646
Less accumulated depreciation	649,011	253,907
	\$ 1,102,932	\$ 686,739

**Note 7. Available for Sale Securities**

The amortized cost and estimated fair value of available for sale 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><u>December 31, 2007</u></b>				
Debt securities	\$ 88,806	\$ 434	\$ 315	\$ 88,925
Equity securities		2,436		2,436
	\$ 88,806	\$ 2,870	\$ 315	\$ 91,361
<b><u>March 31, 2007</u></b>				
Debt securities	\$ 171,862	\$ 151	\$ 465	\$ 171,548
Equity securities		2,659		2,659
	\$ 171,862	\$ 2,810	\$ 465	\$ 174,207

Net unrealized gains on available for sale securities were reported net of tax of \$3.3 million and \$0.8 million at December 31, 2007 and March 31, 2007, respectively.

Maturities of debt securities at fair value as of December 31, 2007, were as follows:

*(in thousands)*

Mature within one year	\$ 7,030
Mature in one to five years	10,729
Mature in five years and later	71,166
	\$ 88,925

**Table of Contents**

Gross gains of \$1.8 million, \$0.8 million and \$0.9 million and gross losses of \$1.5 million, \$1.8 million and \$1.2 million were realized during the nine months ended December 31, 2007 and fiscal years 2007 and 2006, respectively.

The Company also had approximately \$40.6 million of auction rate securities at December 31, 2007. Subsequent to December 31, approximately \$32.0 million of these securities were sold at par value. The remainder of these securities are scheduled to reset at auction in May 2008. During the nine months ended December 31, 2007, no auctions failed.

**Note 8. Goodwill and Other Intangible Assets**

A rollforward of goodwill is as follows:

	<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

	<b>Total</b>
Goodwill balance at March 31, 2006	\$ 102,579
Acquisition of Matrix	505,801
Foreign currency translation and other	4,362
Goodwill balance at March 31, 2007	\$ 612,742

Intangible assets, excluding goodwill, consisted of the following components:

	<b>Weighted Average Life (years)</b>	<b>Original Cost</b>	<b>Accumulated Amortization</b>	<b>Effects of Foreign Currency Translation</b>	<b>Net Book Value</b>
<i>(in thousands)</i>					
<b>December 31, 2007</b>					
Amortized intangible assets:					
Patents and technologies	20	\$ 118,926	\$ 65,578	\$	\$ 53,348
Product rights and licenses	10	2,987,174	152,865	(25,462)	2,808,847
Other intangibles	8	130,060	12,520	(1,029)	116,511

Edgar Filing: MYLAN INC. - Form 10-KT/A

\$ 3,236,160    \$ 230,963    \$ (26,491)    \$ 2,978,706

**March 31, 2007**

Amortized intangible assets:

Patents and technologies	20	\$ 118,927	\$ 61,000	\$	\$ 57,927
Product rights and licenses	8	367,805	86,349		281,456
Other intangibles	14	21,604	8,207		13,397
		\$ 508,336	\$ 155,556	\$	\$ 352,780

Other intangibles consist principally of customer lists and contracts. As a result of the acquisition of a controlling interest in Matrix (see Note 3) 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

## **Table of Contents**

Merck Generics, 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 Statement of Operations, for the nine months ended December 31, 2007 and fiscal years 2007 and 2006 were \$100.7 million, \$22.4 million and \$14.7 million, respectively, and is expected to be \$305.0 million, \$299.8 million, \$292.0 million, \$283.6 million, and \$267.0 million for the years ended 2008 through 2012, respectively.

### **Note 9. Financial Instruments and Risk Management**

#### *Foreign Exchange Risk*

A significant portion of our revenues and earnings is exposed to changes in foreign exchange rates. We seek to manage our 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.

We enter 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. As of December 31, 2007, the more significant financial instruments employed to manage foreign exchange risk are as follows (there were no financial instruments outstanding at March 31, 2007):

875.4 million (\$1.23 billion) of borrowings under the Senior Credit Agreement (Note 10) that is 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 Cumulative Translation Adjustment Component of Other Comprehensive (Loss) Earnings in the Consolidated Statement of Shareholders Equity.

\$345.6 million 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. We recognize the earnings impact of these contracts in Other income, net in the Consolidated Statement of Operations during the terms of the contracts, along with the earnings impact of the items they generally offset.

In conjunction with the acquisition of Merck Generics, 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 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 realized gain of \$85.0 million (net of the premium), for the nine-month period ended December 31, 2007 related to the deal-contingent foreign currency option contract. This amount is included in other income (expense), net in the Consolidated Statement of Earnings. In conjunction with the closing on October 2, 2007 of the acquisition of Merck Generics, this foreign currency option contract was settled (net of the premium).

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 transaction. The Company accounted for this instrument under the provisions of SFAS 133. This instrument did not qualify for

hedge accounting treatment under SFAS 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 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.



**Table of Contents**

All derivative contracts used to manage foreign currency 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 nine months ended December 31, 2007.

*Interest Rate Risk*

Our interest-bearing investments and borrowings are subject to interest rate risk. We invest and borrow primarily on a short-term or variable-rate basis. From time to time, depending on market conditions, we will fix interest rates either through entering into fixed-rate borrowings or through the use of derivative financial instruments.

In 2007, we executed \$1.0 billion of notional interest rate swaps in order to fix the interest rate on a portion of our U.S. dollar debt under the Senior Credit Agreement (Note 10). 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. We recognize the earnings impact of the interest rate swaps in Other income, net in the Company's Consolidated Statement of Operations upon the recognition of the interest related to the hedged items.

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 nine months ended December 31, 2007.

**Note 10. Long-Term Debt**

A summary of long-term debt at December 31, 2007 and March 31, 2007 is as follows:

<i>(in thousands)</i>	<b>December 31, 2007</b>	<b>March 31, 2007</b>
Senior Notes <sup>(A)</sup>	\$ 2,715	\$ 500,000
Credit Facilities <sup>(B)</sup>		450,000
U.S. Tranche A Term Loans <sup>(B)</sup>	312,500	
Euro Tranche A Term Loans <sup>(B)</sup>	516,127	
U.S. Tranche B Term Loans <sup>(B)</sup>	2,556,000	
Euro Tranche B Term Loans <sup>(B)</sup>	773,273	
Revolving Facility <sup>(B)</sup>	300,000	
Senior convertible notes <sup>(C)</sup>	600,000	600,000
Other <sup>(D)</sup>	51,479	226,362
	\$ 5,112,094	\$ 1,776,362
Less: Current portion	405,378	121,430
Total long-term debt	\$ 4,706,716	\$ 1,654,932

<sup>(A)</sup> On August 31, 2007, the Company launched tender offers to purchase for cash any and all of its outstanding 5.750% Senior Notes due 2010 (the 2010 Notes) and 6.375% Senior Notes due 2015 (the 2015 Notes) and

collectively the Senior Notes ) as well as consent solicitations to eliminate various affirmative and negative covenants and events of default contained in the indentures for the Senior Notes, pursuant to the terms of the Offer to Purchase and Consent Solicitation Statement and related Letter of Instructions (the Offer to Purchase ). The holders of the Senior Notes could not tender their Senior Notes without delivering their consent and could not deliver a consent without tendering their Senior Notes. The tender offers and solicitations were made as part of a broader strategy to establish its new global capital structure related to the acquisition of Merck Generics.

Each of the tender offers expired at 10:00 a.m., New York City time, on October 2, 2007, (the Expiration Time ). Holders who validly tendered their Senior Notes after the Consent Payment Deadline and on or prior to

**Table of Contents**

the Expiration Time received the total consideration applicable to the Senior Notes tendered less the consent payment, plus accrued and unpaid interest to, but not including, the Settlement Date.

As of the Expiration Time, approximately \$147.5 million in aggregate principal amount of the 2010 Notes, representing 98.31% of the outstanding 2010 Notes, and \$349.8 million in aggregate principal amount of the 2015 Notes, representing 99.95% of the outstanding 2015 Notes, were tendered. On October 2, 2007, \$497.3 million of the Senior Notes were accepted for purchase and paid for by Mylan in conjunction with the acquisition of Merck Generics. In addition, the amendments that were the subject of the consent solicitations were adopted, thereby eliminating various affirmative and negative covenants and events of default contained in the indentures for the Senior Notes.

(B) The Credit Facilities were repaid in conjunction with the closing of the Merck Generics acquisition.

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 Loan (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 Merck Generics, (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 Merck Generics acquisition the Company borrowed \$325.0 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. On October 19, 2007, the Company paid \$25.0 million on the Revolving Facility reducing the principal amount due to \$300.0 million.

The U.S. Tranche A Term Loans and 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 Term Loans currently bear interest at the Euro Interbank Offered Rate (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 2.75% 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 1.75% 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,

**Table of Contents**

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 are not required to be tested earlier than the quarter ended June 30, 2008.

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 mature on October 2, 2013. The U.S. Tranche B Term Loans and the Euro 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 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 Merck Generics. 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 (see Note 12) 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) reduces the principal amount of the U.S. Tranche A Term Loans of the Company to an aggregate principal amount of \$312.5 million, (ii) increases the principal amount of the U.S. Tranche B Term Loans of the Company to an aggregate principal amount of \$2.56 billion, (iii) creates a new tranche of Euro Tranche A Term Loans of the Euro Borrower in an aggregate principal amount of \$350.4 (\$516.1) million and (iv) reduces the Euro Tranche B Term Loans of the Euro Borrower to an aggregate principal amount of \$525.0 (\$773.3) million.

The new 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.



**Table of Contents**

The Euro Tranche A Term Loans mature on October 2, 2013. The Euro Tranche A Term Loans require amortization payments of 4.4 (\$6.5) million per quarter in 2008, 8.8 (\$13.0) million per quarter in 2009, 13.1 (\$19.3) million per quarter in 2010, 17.5 (\$25.8) million per quarter in 2011, 21.9 (\$32.3) million per quarter in 2012 and 21.9 (\$32.3) million per quarter in 2013. In connection with the decrease in the aggregate principal amount of the U.S. Tranche A Term Loans, the amortization payments required with respect to the U.S. Tranche A Term Loans have been revised to \$3.9 million per quarter in 2008, \$7.8 million per quarter in 2009, \$11.7 million per quarter in 2010, \$15.6 million per quarter in 2011, \$19.5 million per quarter in 2012 and \$19.5 million per quarter in 2013.

The Amended Senior Credit Agreement adds 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.

The interest rate in effect at December 31, 2007, on the outstanding borrowings under the U.S. Tranche A Term Loans was 8.31% and under the U.S. Tranche B Term Loans was 8.24%. The interest rate in effect at December 31, 2007, on the outstanding borrowings under the Euro Tranche A Term Loans and Euro Tranche B Term Loans was 7.75%. At December 31 and March 31, 2007, the Company had outstanding letters of credit of \$172.9 million and \$13.1 million, respectively.

The Company executed \$1.0 billion of notional interest rate swaps in order to fix the interest rate on a portion of our U.S. Dollar debt. These swaps fix a rate of 7.37% on our variable rate debt until December 2010 (see Note 9)

- (C) 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 Convertible Notes). The 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 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 Convertible Notes. The 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.

On March 1, 2007, concurrently with the sale of the 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 Association, London Branch, an affiliate of JPMorgan, each of which the Company refers to as a counterparty. The net cost of the transactions was approximately \$80.6 million. The purchased call options will cover approximately 26,755,853 shares of Mylan common stock, subject to anti-dilution adjustments substantially similar to the anti-dilution adjustments for the Convertible Notes, which under most circumstances represents the maximum number of shares that underlie the 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 26,755,853 shares of Mylan common stock, subject to customary anti-dilution adjustments. The warrants may not be exercised prior to the maturity of the Convertible Notes, subject to certain limited exceptions.

The purchased call options are expected to reduce the potential dilution upon conversion of the 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 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 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



**Table of Contents**

holder of the converted 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 26,755,853 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 Convertible Notes, and will not affect the holders' rights under the Convertible Notes. Holders of the 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* (SFAS No. 138)) and SFAS No. 149, *Amendment of Statement 133 on Derivative Instruments and Hedging Activities* (SFAS No. 149)). 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*) 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*) the instruments are exempted from the scope of SFAS No. 133 and are not subject to the fair value provisions of that standard.

- (D) Other debt consists primarily of Matrix's borrowings consisted primarily of two Euro-denominated Facilities (Facility A and Facility B). On July 5, 2007, Facility A was repaid in the amount of \$82.5 (\$117.8) million. Matrix's effective interest rate for Facility B was EURIBO plus 129 basis points, or 5.861% at December 31, 2007. Facility B is payable over three years in semi-annual installments beginning in October 2007. On September 30, 2007, Matrix paid \$50.0 (\$73.6) million on Facility B reducing the principal amount of the loan to \$32.5 (\$47.9) million. On October 5, 2007, in accordance with the terms of Facility B, Matrix paid \$8.0 (\$11.8) million reducing the principal amount of the loan to \$24.5 (\$36.1) million.

All financing fees associated with the Company's borrowings are being amortized over the life of the related debt. The total unamortized amounts of \$83.0 million and \$26.8 million are included in other assets in the Consolidated Balance Sheets at December 31, 2007 and March 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 new financing for the Merck Generics 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 in the period.

At December 31, 2007, and March 31, 2007, the fair value of the Convertible Notes was approximately \$545.5 million and \$640.4 million, respectively.

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

Principal maturities of the Company's long-term debt for the next five years and thereafter, as of December 31, 2007, are as follows:

(in thousands)

**December 31,**

Edgar Filing: MYLAN INC. - Form 10-KT/A

2008	\$ 405,378
2009	137,022
2010	160,117
2011	199,014
2012	840,445
Thereafter	3,370,118
	\$ 5,112,094

**Table of Contents****Note 11. Income Taxes**

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

	<b>Nine Months Ended December 31, 2007</b>	<b>Fiscal Year Ended March 31,</b>	
		<b>2007</b>	<b>2006</b>
<i>(in thousands)</i>			
Federal:			
Current	\$ 101,659	\$ 242,434	\$ 104,204
Deferred	(29,343)	(46,593)	(22,359)
	72,316	195,841	81,845
State and Puerto Rico:			
Current	9,598	16,746	9,494
Deferred	1,903	(3,740)	(1,276)
	11,501	13,006	8,218
Foreign:			
Current	23,413	174	
Deferred	(47,157)	(1,004)	
	(23,744)	(830)	
Income taxes	\$ 60,073	\$ 208,017	\$ 90,063
Pre-tax (loss) earnings			
Domestic	\$ (413,886)	\$ 586,298	\$ 274,605
Foreign	(667,178)	(160,786)	
Total	\$ (1,081,064)	\$ 425,512	\$ 274,605
Effective tax rate	(5.6)%	48.9%	32.8%

**Table of Contents**

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

	<b>Nine Months Ended</b>		<b>Fiscal Year Ended</b>	
	<b>December 31,</b>		<b>March 31,</b>	
	<b>2007</b>		<b>2007</b>	<b>2006</b>
<i>(in thousands)</i>				
Deferred tax assets:				
Employee benefits	\$	40,038	\$ 16,501	\$ 10,948
Legal matters		59,388	5,048	4,551
Accounts receivable allowances		152,123	126,191	121,235
Inventories			8,859	4,851
Deferred Revenue			43,250	14,488
Investments		4,321	7,256	6,028
Tax credits		3,575	3,112	
Net operating losses		99,289	17,111	1,644
Convertible debt		40,514	44,100	
Other		27,651	3,801	2,783
		426,899	275,229	164,884
Less: Valuation allowance		(76,100)	(18,355)	(1,644)
Total deferred tax assets		350,799	256,874	164,884
Deferred tax liabilities:				
Inventory		16,897		
Plant and equipment		67,425	40,698	21,168
Intangible assets		947,009	98,285	23,977
Investments		9,813	10,779	2,547
Other			1,890	105
Total deferred tax liabilities		1,041,144	151,652	47,797
Deferred tax (liability) asset, net	\$	(690,345)	\$ 105,222	\$ 117,087
Classification in the Consolidated Balance Sheets:				
Deferred income tax benefit current	\$	192,113	\$ 145,343	\$ 137,672
Deferred income tax liability current		(24,344)		
Deferred income tax benefit noncurrent		18,703	45,779	
Deferred income tax liability noncurrent		(876,817)	(85,900)	(20,585)
Deferred tax asset, net	\$	(690,345)	\$ 105,222	\$ 117,087

**Table of Contents**

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

<b>Fiscal Year Ended March 31,</b>	<b>2007</b>	<b>Fiscal Year Ended</b>	
	<b>Nine Months Ended December 31, 2007</b>	<b>2007</b>	<b>March 31, 2006</b>
Statutory tax rate	35.0%	35.0%	35.0%
State and Puerto Rico income taxes	(1.1)%	4.1%	4.0%
State and Puerto Rico tax credits	0.5%	(1.3)%	(1.5)%
Research and Development tax credits	0.3%	(0.3)%	(1.0)%
Resolution of prior year tax positions	0.0%	0.0%	2.7%
Acquired In-Process R & D	(41.1)%	12.1%	0.0%
Effect of foreign operations	1.8%	0.0%	0.0%
Other items	(1.0)%	(0.7)%	(1.0)%
Effective tax rate	(5.6)%	48.9%	32.8%

*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 \$76.1 million. Approximately \$36.2 million of the valuation allowance will result in a reduction to goodwill if such deferred tax assets are ever realized. The remainder of the increase in the valuation allowance is due to net operating losses.

*Net Operating Losses*

As of December 31, 2007, the Company has net operating loss carryforwards for international and U.S. state income tax purposes of approximately \$465.2 million which will expire in fiscal years 2016 through 2028. Of these loss carryforwards, there is an amount of \$154.8 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 \$3,000 each taxable year. In addition, the Company has foreign net operating loss carryforwards of approximately \$310.4 of which \$214.2 can be carried forward indefinitely with the remainder expiring in years 2008 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 controlling interest in Merck Generics. Of the purchase price, \$1.2 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 new tax grant was negotiated with the government of Puerto Rico extending tax incentives until fiscal 2010. This grant exempts all earnings during this grant period from tollgate tax upon repatriation of cash to the United States. In fiscal 2007 and fiscal

**Table of Contents**

2004, \$46,500 and \$100,000 of cash from post-fiscal 2000 earnings, respectively, was repatriated to the United States. Pursuant to the terms of our new tax grant, no tollgate tax was due for these repatriations.

*Federal Tax credits, Certain Deductions and Ongoing IRS Examinations*

Federal tax credits result principally from operations in Puerto Rico and from qualified research and development expenditures, including orphan drug research. State tax credits are comprised mainly of awards for expansion and wage credits at our manufacturing facilities and research credits awarded by certain states. State income taxes and state tax credits are shown net of the federal tax effect.

Under Section 936 of the U.S. Internal Revenue Code ( IRC ), Mylan was a grandfathered entity and was entitled to the benefits under such statute through fiscal 2006. Our Section 936 federal tax credits totaled approximately \$1,461 in fiscal 2006 and \$3,874 in fiscal 2005. The decrease in the credit in fiscal 2006 was offset by newly-enacted IRC Section 199, Deduction for Domestic Production Activities, which resulted in a tax benefit of approximately \$3,000 in fiscal 2006. The tax benefit from the Deduction for Domestic Production Activities was approximately \$7,050 for the nine months ended December 31, 2007.

The Internal Revenue Service ( IRS ) completed its federal tax audit for fiscal years 2002 through 2004 in the first quarter of fiscal 2007. Tax and interest related to the negotiated settlement of certain federal tax positions as a result of those audits was recorded as of March 31, 2006. Beginning with fiscal 2007, Mylan became a voluntary participant in the IRS Compliance Assurance Process ( CAP ) which results in real-time federal issue resolution. In connection with the CAP program, the IRS commenced the audits of Mylan s tax returns for fiscal 2005 and 2006. We expect to complete the fiscal 2005 and 2006 audits in the first quarter of 2008. The fiscal 2007 CAP return was filed in the third quarter of calendar year 2007 and a Partial Acceptance Letter was received. We did not reach agreement on a single issue that will be audited in accordance with regular IRS processes. Given that this issue is being decided by IRS National Office, the timing of settlement cannot be estimated at this time. Tax and interest continue to be accrued related to certain tax positions.

*Adoption of 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, we 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 April 1, 2007, after the implementation of FIN 48, the Company s liability for unrecognized tax benefits was \$42.9 million, excluding liabilities for interest and penalties. In addition, at April 1, 2007, liabilities for accrued

interest and penalties relating to the unrecognized tax benefits totaled \$6.3 million. As of December 31, 2007, if the Company were to recognize these benefits, the effective tax rate would reflect a favorable net impact of \$24.1 million.

The Company acquired Merck Generics in a transaction that was consummated on October 2, 2007 and a FIN 48 liability of \$39.9 million, excluding interest and penalties of \$16.4 million, was recorded in the opening



**Table of Contents**

balance sheet. Under the SPA for Merck Generics, a tax indemnity exists for certain pre-effective date tax liabilities. The benefit of any indemnity claim will be recorded at the time stipulated under the SPA. No tax indemnity benefit has been recorded at December 31, 2007.

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

The tax years March 31, 2005 through March 31, 2007 remain open to examination by the Internal Revenue Service. The major state taxing jurisdictions applicable to the Company remain open from fiscal 2004 through fiscal 2007. The major taxing jurisdictions for the Company internationally remain open from 2001 through 2007.

A reconciliation of the unrecognized tax benefits for the year ended December 31, 2007 follows:

	<b>Unrecognized Tax Benefits</b>	
<i>(in thousands)</i>		
Balance as of April 1, 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 for Merck Generics entities		39,600
Balance as of December 31, 2007	\$	77,600

In accordance with our accounting policy, both before and after adoption of FIN 48, interest expense and penalties related to income taxes are included in the Other income, net line of our Consolidated Statements of Operations.

It is anticipated that the amount of unrecognized tax benefits will decrease in the next twelve months. We foresee issues involving purchase accounting, state tax audits and the expiration of certain statutes of limitations having a significant impact on the results of operations, cash flows or the financial position of the Company. We expect the range of the decrease of our existing reserve to decrease between \$15.0 million and \$30.0 million. We do not anticipate significant increases to the reserve within the next twelve months.

**Note 12. 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.

On March 1, 2007, the Company entered into a Purchase Agreement (the Common Stock Purchase Agreement ) with Merrill Lynch & Co. and J.P. Morgan Securities Inc., as representatives of the underwriters named therein, relating to the sale of 26,162,500 shares of common stock at a price of \$19.50 per share. Upon completion of this transaction in the Company's fourth quarter of fiscal 2007, the Company received proceeds of approximately \$488.8 million, net of underwriter's discounts and offering expenses of approximately \$21.1 million.

On March 1, 2007, concurrently with the sale of the Convertible Notes, (see Note 10) 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 Association,

**Table of Contents**

London Branch, an affiliate of JPMorgan, each of which we refer to as a counterparty. The net cost of the transactions was approximately \$80.6 million. The purchased call options will cover approximately 26,755,853 shares of our common stock, subject to anti-dilution adjustments substantially similar to the anti-dilution adjustments for the Convertible Notes, which under most circumstances represents the maximum number of shares that underlie the Convertible Notes. Concurrently with entering into the purchased call options, we entered into warrant transactions with the counterparties. Pursuant to the warrant transactions, we will sell to the counterparties warrants to purchase in the aggregate approximately 26,755,853 shares of our common stock, subject to customary anti-dilution adjustments. The warrants may not be exercised prior to the maturity of the Convertible Notes, subject to certain limitations.

The purchased call options are expected to reduce the potential dilution upon conversion of the Convertible Notes in the event that the market value per share of our common stock at the time of exercise is greater than approximately \$22.43, which corresponds to the initial conversion price of the Convertible Notes. The sold warrants have an exercise price that is 60.0% higher than the price per share of \$19.50 at which we offered our common stock in a concurrent equity offering described above. If the market price per share of our common stock at the time of conversion of any Convertible Notes is above the strike price of the purchased call options, the purchased call options will, in most cases, entitle us to receive from the counterparties in the aggregate the same number of shares of our common stock as we would be required to issue to the holder of the converted Convertible Notes. Additionally, if the market price of our common stock at the time of exercise of the sold warrants exceeds the strike price of the sold warrants, we will owe the counterparties an aggregate of approximately 26,755,853 shares of our common stock. The purchased call options and sold warrants may be settled for cash at our 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 Convertible Notes and will not affect the holders' rights under the Convertible Notes. Holders of the 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, *Accounting for Derivative Instruments and Hedging Activities (as amended by SFAS No. 138 and SFAS No. 149)*. 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*) 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*) the instruments are exempted out of the scope of SFAS No. 133 and are not subject to the mark to market provisions of that standard.

Following the closing of the Matrix transaction, (see Note 3) 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 these selling shareholders.

In fiscal 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 6.50% 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.

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 when declared by the Board of Directors. 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.

**Table of Contents**

The November 2007 offerings generated net proceeds of \$2.82 billion after underwriters discounts and expenses. The Company used the net proceeds of the offerings plus cash on hand to repay the \$2.85 billion Interim Term Loans that were borrowed to finance in part its acquisition of Merck Generics (see Note 10).

On January 30, 2008, the Company declared a dividend to the preferred stock shareholders for the period that the preferred shares were outstanding, that was paid on February 15, 2008. Accordingly, Mylan recorded a dividend payable of \$16.0 million at December 31, 2007. We expect to pay dividends in cash on February 15, May 15, August 15, and November 15 of each year prior to November 15, 2010. Under certain circumstances, we 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 13. Stock Option Plan**

On July 25, 2003, Mylan's shareholders approved the *2003 Long-Term Incentive Plan*, and approved certain amendments on July 28, 2006 (the *2003 Plan*). Under the 2003 Plan, 22,500,000 shares of common stock are reserved 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 generally granted at the market price of the shares underlying the options at the date of the grant and generally become exercisable over periods ranging from three to four years and generally expire in ten years.

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

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, 2005	22,301,788	\$ 14.17
Options granted	5,780,123	17.61
Options exercised	(4,729,113)	12.03
Options forfeited	(1,994,128)	18.65
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
Vested and expected to vest at December 31, 2007	20,310,689	\$	16.12
Options exercisable at December 31, 2007	12,849,800	\$	15.41

As of December 31, 2007, options outstanding, options vested and expected to vest, and options exercisable had average remaining contractual terms of 6.15 years, 6.09 years and 4.79 years, respectively. Also at December 31, 2007, options outstanding, options vested and expected to vest and options exercisable had aggregate intrinsic values of \$13.5 million, \$13.5 million, and \$13.5 million, respectively.

**Table of Contents**

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 March 31, 2007	211,316	\$	23.10
Granted	1,116,873		15.85
Released			
Forfeited	(32,842)		19.01
Nonvested at December 31, 2007	1,295,347	\$	16.95

Of the 1,116,873 awards granted during the nine months ended December 31, 2007, 774,427 vest ratably over four years and the remaining 342,446 vest ratably over three years.

As of December 31, 2007, the Company had \$42.5 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 2.12 years. The total intrinsic value of options exercised during the nine months ended December 31, 2007 was \$3.2 million. The total fair value of all options which vested during the nine months ended December 31, 2007 and fiscal years 2007 and 2006 was \$0.1 million, \$51.4 million and \$27.9 million, respectively.

With respect to options granted under the Company's stock-based compensation plan, the fair value of each option grant was estimated at the date of grant using the Black-Scholes option pricing model. Black-Scholes utilizes 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>Nine Months Ended December 31, 2007</b>	<b>Fiscal Years Ended March 31, 2007 2006</b>	
Volatility	30.8%	34.0%	38.70%
Risk-free interest rate	4.6%	4.8%	4.00%
Dividend yield	0.0%	1.1%	1.30%
Expected term of options (in years)	5.0	4.5	4.5
Forfeiture rate	3.0%	3.0%	0%
Weighted average grant date fair value per option	\$ 5.60	\$ 6.90	\$ 5.92

Pro forma disclosure of net income and earnings per share had the Company applied the fair value recognition provisions of SFAS No. 123 to stock-based compensation prior to April 1, 2006 using the above assumptions is presented in Note 2.

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 nine-month period ended December 31, 2007, no options were granted under the Matrix plan. As of December 31, 2007, there were 315,823 options exercisable.



**Table of Contents****Note 14. 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 Merck Generics. No substantial plan changes or terminations have been made related to any acquired defined benefit plans. Benefit formulas are based on varying criteria on a plan by plan basis. Our 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. We fund 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 not material at 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, 2007 and March 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 158 ). The provisions of SFAS 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.

*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 Merck Generics 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 Statement of Earnings when they are due. Total employer contributions to defined contribution plans were \$12.2 million for the nine months ended December 31, 2007, and \$16.5 million, and \$12.2 million for the fiscal years ended March 31, 2007, and 2006. Contributions related to plans of the acquired businesses of Matrix and Merck Generics have been included in the Consolidated Statement of Earnings since the respective dates of acquisition.

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.

**Table of Contents**

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 that have employees who are unionized or part of works councils or trade unions. These worksites are primarily concentrated in central Europe and India. These employees represented approximately 17% of the Company's total workforce at December 31, 2007.

**Note 15. Segment Information**

The Company 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, while the Matrix Segment engages mainly in the manufacture and sale of APIs and the distribution of branded generic products. Additionally, certain general and administrative expenses, as well as litigation settlements, and non-operating income and expenses are reported in Corporate/Other.

The Company's chief operating decision maker evaluates the performance of its reportable segments based on net revenues and segment earnings from operations. Items below the earnings from operations line of the consolidated statements of operations are not presented by segment, since they are excluded from the measure of segment profitability reviewed by the Company's chief operating decision maker. 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. 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. For the Generics, Specialty, and Matrix Segments, segment earnings from operations (Segment profitability (loss)) represents segment gross profit less direct research and development expenses and direct selling, general and administrative expenses. Amortization of intangible assets as well as certain purchase accounting related items such as the write-off of in-process research and development and the amortization of the inventory step-up are excluded from segment profitability.

<b>Nine Months Ended December 31, 2007</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>
Net revenues					
Third party	\$ 1,796,587	\$ 102,126	\$ 264,230	\$	\$ 2,162,943
Intersegment	563	3,401	29,547	(33,511)	
Total	1,797,150	105,527	293,777	(33,511)	\$ 2,162,943
Segment profitability (loss)	\$ 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>
-----------------------	-----------------------------	------------------------------	---------------------------	--------------------------------------	---------------------

Edgar Filing: MYLAN INC. - Form 10-KT/A

Net revenues					
Third party	\$	1,507,535	\$	\$	79,412
Intersegment				\$	(16,389)
					\$ 1,586,947
Total		1,507,535		95,801	(16,389)
Segment profitability (loss)	\$	712,685	\$	\$	8,578
					(293,709)
					427,554

**Table of Contents****Fiscal Year Ended**

<b>March 31, 2006</b>	<b>Generics Segment</b>	<b>Specialty Segment</b>	<b>Matrix Segment</b>	<b>Corporate/Other<sup>(1)</sup></b>	<b>Consolidated</b>
Net revenues					
Third party	\$ 1,240,011	\$	\$	\$	\$ 1,240,011
Intersegment					
Total	1,240,011				1,240,011
Segment profitability (loss)	465,465			(178,077)	287,388

<sup>(1)</sup> Includes corporate overhead, intercompany eliminations, amortization of intangible assets and certain purchase accounting related items (such as the write-off of in-process research and development and the amortization of the inventory step-up) and charges not directly attributable to segments.

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

<i>(in thousands)</i>	<b>Nine Months Ended December 31, 2007</b>	<b>Fiscal Year Ended March 31,</b>	
		<b>2007</b>	<b>2006</b>
Cardiovascular	\$ 587,020	\$ 463,610	\$ 422,727
Central nervous system	584,466	579,814	475,898
Dermatology	44,718	58,066	72,843
Gastrointestinal	149,804	59,655	46,701
Endocrine and Metabolic	198,875	133,967	84,048
Renal and Genitourinary	122,484	148,494	63,967
Other <sup>(1)</sup>	475,576	143,341	73,827
	\$ 2,162,943	\$ 1,586,947	\$ 1,240,011

<sup>(1)</sup> 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 (including India). Net revenues are classified based on the geographic location of the customers and are as follows:

<b>Nine Months Ended</b>	<b>Fiscal Year Ended March 31,</b>
--------------------------	--

<i>(in thousands)</i>	<b>December 31, 2007</b>	<b>2007</b>	<b>2006</b>
Net external revenues			
The Americas			
United States	\$ 1,342,564	\$ 1,506,419	\$ 1,233,990
Other Americas	68,117	2,622	213
Europe	243,713	50,958	2,694
Asia	508,549	26,948	3,114
	\$ 2,162,943	\$ 1,586,947	\$ 1,240,011

101

**Table of Contents****Note 16. Commitments**

The Company leases certain real property under various operating lease arrangements that expire over the next eight years. These leases generally provide the Company with the option to renew the lease at the end of the lease term. The Company also entered into agreements to lease vehicles for use by certain key employees which are typically 24 to 36 months. For the nine months ended December 31, 2007 and fiscal years 2007 and 2006, the Company made lease payments of \$9.3 million, \$3.9 million and \$3.7 million, respectively.

Future minimum lease payments under these commitments are as follows:

<b>December 31,</b> <i>(in thousands)</i>	<b>Operating Leases</b>
2008	\$ 18,446
2009	15,183
2010	11,567
2011	6,738
2012	5,818
Thereafter	11,405
	\$ 69,157

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.

The Company has also entered into employment and other agreements with certain executives that provide for compensation and certain other benefits. These agreements provide for severance 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 17. 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 we acquired Merck Generics. An adverse outcome in any of these proceedings could have a material adverse effect on the Company's financial position and results of operations.

*Omeprazole*

In fiscal 2001, Mylan Pharmaceuticals Inc. ( MPI ) filed an Abbreviated New Drug Application ( ANDA ) seeking approval from the U.S. Food and Drug Administration ( FDA ) to manufacture, market and sell omeprazole delayed-release capsules and 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 Inc. ( 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



**Table of Contents**

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, which could result in treble damages, injunctive relief, attorneys' fees, costs of litigation and such further relief as the court deems just and proper. MPI has certain indemnity obligations to Esteve in connection with this litigation. MPI, Esteve and the other generic manufacturers who are co-defendants in the case filed motions for summary judgment of non-infringement and patent invalidity. On January 12, 2006, those motions were denied. 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.

*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 ( D.C. ) in the amount of approximately \$12 million which has been accrued for by the Company. The jury found 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 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 \$7.5 million plus additional interest accruing daily. The Company and its co-defendants have appealed to the U.S. Court of Appeals for the D.C. Circuit.

*Pricing and Medicaid Litigation*

On June 26, 2003, MPI and UDL Laboratories Inc. ( 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, 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 a series of 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 ( AWP ) 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, 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, with the exception of the Florida, Iowa, Idaho, South Carolina

## **Table of Contents**

and Utah AG actions, Mylan, MPI and/or UDL have answered the respective complaints denying liability. Mylan and its subsidiaries intend to defend each of these actions vigorously.

In addition, by letter dated January 12, 2005, MPI was notified by the U.S. Department of Justice of an investigation concerning MPI's calculations of Medicaid drug rebates. MPI is cooperating fully with the government's investigation.

Dey, Inc. has also been named in suits brought by the state AG's of Alaska, Arizona, California, Florida, Illinois, Iowa, Kentucky, Mississippi, 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 and a number of these cases remain pending. Additionally, U.S. federal government filed a claim against Dey, Inc. in September 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.

### *Modafinil Antitrust Litigation and FTC Inquiry*

Beginning in April 2006, Mylan, along with four other drug manufacturers, has been named in a series of 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 Mylan Technologies Inc. (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. Mylan is not named as a defendant in the lawsuit, although the complaint includes allegations pertaining to the Mylan/Cephalon settlement.

### *Merck Generics Litigation*

Generics (UK) Ltd. has been alleged of having been involved in pricing agreements pertaining to certain drugs during the years 1996 and 2000. Generics (UK) Ltd. was able to settle claims for damages asserted by the Health Service in England and Wales out of court, which does not constitute any admission of liability. Additional claims were filed against Generics (UK) Ltd. as of December 31, 2007 by health authorities in Scotland and Northern Ireland totaling £20.0 (\$39.9) million plus interest. In addition to these civil claims, criminal proceedings were also filed in Southwark Crown Court in April 2006 against Generics (UK) Ltd. and the people responsible for running this company as of December 31, 2007.

The Company has approximately \$132.3 million recorded in other liabilities related to the pricing litigation involving Dey and Generics (UK) Ltd. As stated above, in conjunction with the Merck Generics acquisition, this litigation has been indemnified by Merck KGaA under the Share Purchase Agreement. As a result, the Company has recorded approximately \$137.1 million in other assets.

### *Other Litigation*

The Company is involved in various other legal proceedings that are considered normal to its business. While it is not feasible to predict the ultimate outcome of such other proceedings, the Company believes that the ultimate outcome of such other proceedings will not have a material adverse effect on its financial position or results of operations.

**Table of Contents**

**Note 18. Subsequent Events**

On February 27, 2008, Mylan executed an agreement with Forest Laboratories, whereby Mylan sold its rights to Nebivolol, an FDA approved product for the treatment of hypertension which is marketed by Forest under the Brand name Bystolic(TM). Mylan will receive a one-time cash payment of \$370.0 million (within ten business days from the execution of the agreement) and will retain its contractual royalties for three years, through calendar 2010.

**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.

During the nine-month period ended December 31, 2007, the Company acquired the generics business of Merck KGaA (Merck Generics). For purposes of Management's evaluation of the Company's internal control over financial reporting as of December 31, 2007, we have elected to exclude from our assessment, the internal control over financial reporting at the subsidiaries acquired from Merck KGaA, which were acquired on October 2, 2007 and whose financial statements constituted approximately 18% of our consolidated assets and 32% of consolidated revenues as of and for the nine-months ended December 31, 2007. This acquired business will be included in management's assessment of the effectiveness of the Company's internal controls over financial reporting as of December 31, 2008.

In conducting the December 31, 2007 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, 2007, the Company's internal control over financial reporting was effective.

Our independent registered public accounting firm, Deloitte & Touche LLP, has audited the effectiveness of our internal control over financial reporting. Deloitte & Touche LLP's opinion on the effectiveness of our internal control over financial reporting appears on page 108 of this Transition Report on 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, 2007 and March 31, 2007, and the related consolidated statements of operations, shareholders' equity, and cash flows for the nine months ended December 31, 2007 and for each of the two years in the period ended March 31, 2007. Our audits also included the 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 these 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, 2007, and March 31, 2007, and the results of their operations and their cash flows for the nine months ended December 31, 2007 and for each of the two years in the period ended March 31, 2007 in conformity with accounting principles generally accepted in the United States of America. Also, in our opinion, such 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 2 to the consolidated financial statements, effective April 1, 2006, the Company adopted FASB Statement No. 123R, *Share-Based Payment*. As discussed in Note 11 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, 2007 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 29, 2008 expressed an unqualified opinion on the Company's internal control over financial reporting.

/s/ Deloitte & Touche LLP  
Pittsburgh, Pennsylvania  
February 29, 2008

**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, 2007, based on criteria established in *Internal Control – Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. As described in Management’s Report on Internal Control over Financial Reporting, management excluded from its assessment the internal control over financial reporting at the subsidiaries acquired from Merck KGaA, which were acquired on October 2, 2007 and whose financial statements constitute 18% of consolidated assets and 32% of total revenues of the consolidated financial statement amounts as of and for the nine months ended December 31, 2007. Accordingly, our audit did not include the internal control over financial reporting at the subsidiaries acquired from Merck KGaA. 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, 2007, based on the criteria established in *Internal Control – Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission.





**Table of Contents**

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated financial statements and financial statement schedule as of and for the nine months ended December 31, 2007 of the Company and our report dated February 29, 2008 expressed an unqualified opinion on those financial statements and financial statement schedule and included explanatory paragraphs relating to the Company's adoption of FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes* and an Interpretation of FASB Statement No. 109 and a change in the Company's fiscal year.

/s/ Deloitte & Touche LLP  
Pittsburgh, Pennsylvania  
February 29, 2008

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

(unaudited, in thousands, except per share data)

<b>Nine Months Ended December 31, 2007</b>	<b>Three Month Period Ended</b>		
	<b>June 30, 2007</b>	<b>September 30, 2007</b>	<b>December 31, 2007</b>
Total revenues	\$ 546,321	\$ 477,091	\$ 1,155,349
Gross profit	296,708	221,641	356,099
Net earnings (loss) available to common shareholders	79,727	149,827	(1,383,577) <sup>(4)</sup>
Earnings per share <sup>(1)</sup> :			
Basic	\$ 0.32	\$ 0.60	\$ (5.04) <sup>(4)</sup>
Diluted	\$ 0.32	\$ 0.60	\$ (5.04) <sup>(4)</sup>
Share prices <sup>(2)</sup> :			
High	\$ 22.64	\$ 18.19	\$ 16.87
Low	\$ 18.19	\$ 14.00	\$ 13.25

<b>Fiscal 2007</b>	<b>Three Month Period Ended</b>			
	<b>June 30, 2006</b>	<b>September 30, 2006</b>	<b>December 31, 2006</b>	<b>March 31, 2007</b>
Total revenues	\$ 356,140	\$ 366,656	\$ 401,761	\$ 487,262
Gross profit	188,200	196,090	224,531	234,847
Net earnings	75,587	77,541	135,445	(71,289) <sup>(3)</sup>
Earnings per share <sup>(1)</sup> :				
Basic	\$ 0.36	\$ 0.37	\$ 0.64	\$ (0.31) <sup>(3)</sup>
Diluted	\$ 0.35	\$ 0.36	\$ 0.63	\$ (0.31) <sup>(3)</sup>
Share prices <sup>(2)</sup> :				
High	\$ 23.55	\$ 23.05	\$ 22.07	\$ 22.61
Low	\$ 20.00	\$ 19.06	\$ 19.91	\$ 19.42

(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.

(2) Closing prices as reported on the New York Stock Exchange (NYSE).

(3) The results for the three months ended March 31, 2007, include the results of Matrix since its acquisition on January 8, 2007, and certain purchase accounting adjustments, including \$147.0 million related to acquired in-process research and development.

(4) The results for the three months ended December 31, 2007, include the results of Merck Generics since its acquisition on October 2, 2007, and certain purchase accounting adjustments, including \$1.27 billion related to acquired in-process research and development.

**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

## **Table of Contents**

operation of the Company's disclosure controls and procedures as of December 31, 2007. Based upon that evaluation, the Chief Executive Officer and the Chief Financial Officer concluded that the Company's disclosure controls and procedures were effective.

During the quarter ended December 31, 2007, the Company completed its acquisition of Merck Generics, discussed in Management's Report on Internal Control over Financial Reporting on page 106, and implemented a new consolidation system to enhance the Company's worldwide consolidation function.

Management has not identified any other changes in the Company's internal control over financial reporting during this quarter that has materially affected, or is 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 106. The effectiveness of the Company's internal control over financial reporting as of December 31, 2007, has been audited by Deloitte & Touche LLP, an independent registered public accounting firm, as stated in their report which is on pages 108-109.

### **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 2008 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 this ITEM 11 will be set forth under the caption Executive Compensation in our 2008 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 this 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 2008 Proxy Statement and is incorporated herein by reference.

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

The information required by this ITEM 13 will be set forth under the caption "Certain Relationships and Related Transactions" in our 2008 Proxy Statement and is incorporated herein by reference.

**ITEM 14. Principal Accounting Fees and Services**

The information required by this ITEM 14 will be set forth under the captions "Independent Registered Public Accounting Firm's Fees" and "Audit Committee Pre-Approval Policy" in our 2008 Proxy Statement and is incorporated herein by reference.

**Table of Contents****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 LABORATORIES INC.**  
**SCHEDULE II VALUATION AND QUALIFYING ACCOUNTS**  
**(in thousands)**

Description	Beginning Balance	Additions/Deductions		Additons Charged to Other Accounts	Deductions	Ending Balance
		Charged to Costs and Expenses				
Allowance for doubtful accounts: Nine months ended December 31, 2007	\$ 15,149	\$ 9,959	\$ 22,872*	\$ (258)	\$ 47,722	
Fiscal 2007	\$ 10,954	\$ (500)	\$ 4,778**	\$ (83)	\$ 15,149	
Fiscal 2006	\$ 7,340	\$ 3,614	\$	\$	\$ 10,954	

\* Allowance recorded as part of the Merck Generics 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) 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.

- 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.



**Table of Contents**

- 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.
- 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) 2003 Long-Term Incentive Plan, filed as Appendix A to Definitive Proxy Statement on Schedule 14A, filed with the SEC on June 23, 2003, and incorporated herein by reference.\*
- 10.4(b) Form of Stock Option Agreement under the Mylan Laboratories Inc. 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 Mylan Laboratories Inc. 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 Mylan Laboratories Inc. 2003 Long-Term Incentive Plan, filed as Exhibit 10.4(d) to Form 10-K for the fiscal year ended March 31, 2006, and incorporated herein by reference.\*
- 10.4(e) Amendment No. 2 to Mylan Laboratories Inc. 2003 Long-Term Incentive Plan, filed as Exhibit 10.4(e) to Form 10-K for the fiscal year ended March 31, 2006, and incorporated herein by reference.\*
- 10.5 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.\*
- 10.6(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.\*
- 10.6(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.\*
- 10.7(a) Executive Employment Agreement dated as of July 1, 2004, between the registrant and Stuart A. Williams, filed as Exhibit 10.30 to Form 10-Q/A for the quarter ended September 30, 2004, and incorporated herein by reference.\*
- 10.7(b) Amendment No. 1 to Executive Employment Agreement dated as of April 3, 2006, between the registrant and Stuart A. Williams filed as Exhibit 10.9(b) to Form 10-K for the fiscal year ended March 31, 2006, and incorporated herein by reference.\*
- 10.7(c) Amendment No. 2 to Executive Employment Agreement dated as of March 31, 2007, between the registrant and Stuart A. Williams.\*
- 10.8(a)

Edgar Filing: MYLAN INC. - Form 10-KT/A

Form of Employment Agreement dated as of December 15, 2003, between the registrant and certain executive officers (other than named executive officers), filed as Exhibit 10.18 to Form 10-Q for the quarter ended December 31, 2003, and incorporated herein by reference.\*

- 10.8(b) Form of Amendment No. 1 to Executive Employment Agreement dated as of April 3, 2006, between the registrant and certain executive officers (other than named executive officers) filed as Exhibit 10.10(b) to Form 10-K for the fiscal year ended March 31, 2006, and incorporated herein by reference.\*

**Table of Contents**

- 10.9(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.\*
- 10.9(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.\*
- 10.10(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.\*
- 10.10(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.\*
- 10.11(a) Retirement Benefit Agreement dated as of December 31, 2004, between the registrant and Stuart A. Williams, filed as Exhibit 10.9 to Form 10-Q for the quarter ended December 31, 2004, and incorporated herein by reference.\*
- 10.11(b) Amendment No. 1 to Retirement Benefit Agreement dated as of April 3, 2006, between the registrant and Stuart A. Williams filed as Exhibit 10.13(b) to Form 10-K for the fiscal year ended March 31, 2006, and incorporated herein by reference.\*
- 10.12 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.\*
- 10.13(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.\*
- 10.13(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.\*
- 10.14 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.\*
- 10.15(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.\*
- 10.15(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.\*
- 10.15(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.\*
- 10.16(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.\*
- 10.16(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.\*
- 10.16(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.\*

Edgar Filing: MYLAN INC. - Form 10-KT/A

- 10.17 Amended and Restated Transition and Succession Agreement dated as of April 3, 2006, between the registrant and Stuart A. Williams filed as Exhibit 10.23 to Form 10-K for the fiscal year ended March 31, 2006, and incorporated herein by reference.\*
- 10.18(a) Form of Transition and Succession Agreement dated as of December 15, 2003, with certain executive officers (other than named executive officers), filed as Exhibit 10.24 to Form 10-Q for the quarter ended December 31, 2003, and incorporated herein by reference.\*

**Table of Contents**

10.18(b)	Amendment No. 1 to Form of Transition and Succession Agreement dated as of April 3, 2006, with certain executive officers (other than named executive officers) filed as Exhibit 10.24(b) to Form 10-K for the fiscal year ended March 31, 2006, and incorporated herein by reference.*
10.19	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.*
10.20	Supplemental Health Insurance Program For Certain Officers of Mylan Laboratories Inc., 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.*
10.21	Mylan Laboratories Inc. Severance Plan, filed as Exhibit 10.12 to Form 10-Q for the quarter ended December 31, 2004, and incorporated herein by reference.*
10.22	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.*
10.23	Description of the registrant's Director Compensation Arrangements in effect as of May 21, 2007 filed as Exhibit 10.26 to Form 10-K for the year ended March 31, 2007, and incorporated herein by reference.*
10.24	Share Purchase Agreement, dated as of August 28, 2006, by and among the registrant, MP Laboratories (Mauritius) Ltd, Prasad Nimmagadda, Prasad Nimmagadda-HUF, G2 Corporate Services Limited, India Newbridge Investments Limited, India Newbridge Partners FDI Limited, India Newbridge Coinvestment Limited, Maxwell (Mauritius) Pte. Limited and Spandana Foundation filed as Exhibit 10.2 to Form 10-Q for the quarter ended September 30, 2006, and incorporated herein by reference.
10.25	Shareholders Agreement, dated as of August 28, 2006, by and among the registrant, India Newbridge Investments Limited, India Newbridge Partners FDI Limited, India Newbridge Coinvestment Limited, Maxwell (Mauritius) Pte. Limited and Prasad Nimmagadda filed as Exhibit 10.3 to Form 10-Q for the quarter ended September 30, 2006, and incorporated herein by reference.
10.26	Agreement Regarding Consulting Services and Shareholders Agreement dated as of December 31, 2007 by and among the registrant, MP Laboratories (Mauritius) Ltd, Prasad Nimmagadda and G2 Corporate Services Limited.
10.27(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.
10.27(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.
10.28	Amended and Restated Credit Agreement dated as of December 20, 2007 by and among the registrant, Mylan Luxembourg 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.
12.1	Ratio of Earnings to Fixed Chargers, filed as Exhibit 12.1 to Form 8-K/A filed with the SEC on November 1, 2007, and incorporated herein by reference.
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.



**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 March 7, 2008.

Mylan Inc.

by /s/ EDWARD J. BORKOWSKI

Edward J. Borkowski  
Executive Vice President and  
Chief Financial Officer

116

---

**Table of Contents**

**EXHIBIT INDEX**

- 10.26 Agreement Regarding Consulting Services and Shareholders Agreement dated as of December 31, 2007 by and among the registrant, MP Laboratories (Mauritius) Ltd, Prasad Nimmagadda and G2 Corporate Services Limited.
- 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.