

MYLAN LABORATORIES INC

Form 10-K

May 16, 2006

**Table of Contents**

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, DC 20549  
FORM 10-K**

**Annual Report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934  
For the Fiscal Year Ended March 31, 2006**

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

**Commission File No. 1-9114  
MYLAN LABORATORIES 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                           |

**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.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer or a non-accelerated filer. See definition of accelerated filer and large accelerated filer in Rule 12b-2 of the Exchange Act. (Check one):  
Large Accelerated filer  Accelerated Filer  Non-Accelerated Filer

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 30, 2005, the last business day of the registrant's most recently completed

second fiscal quarter, was approximately \$4,021,304,067.

The number of outstanding shares of common stock of the registrant as of May 8, 2006, was 210,230,665.

**DOCUMENTS INCORPORATED BY REFERENCE**

Incorporated by reference into Part III, Items 10-14 of this Form are portions of the registrant's Proxy Statement for the 2006 Annual Meeting of Shareholders, which will be filed with the Securities and Exchange Commission within 120 days after the end of the registrant's fiscal year ended March 31, 2006.

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**MYLAN LABORATORIES INC.  
INDEX TO FORM 10-K  
For the Fiscal Year Ended March 31, 2006**

|   | <b>Page</b> |
|---|-------------|
| <u><b>PART I</b></u>  |             |
| <u>ITEM 1. Business</u>   | 3           |
| <u>Overview of Our Business</u>   | 3           |
| <u>Product Development</u>  | 5           |
| <u>Patents, Trademarks and Licenses</u>   | 7           |
| <u>Customers and Marketing</u>  | 7           |
| <u>Competition</u>  | 8           |
| <u>Product Liability</u>  | 8           |
| <u>Raw Materials</u>  | 8           |
| <u>Government Regulation</u>  | 9           |
| <u>Seasonality</u>  | 10          |
| <u>Environment</u>  | 10          |
| <u>Employees</u>  | 10          |
| <u>Backlog</u>  | 10          |
| <u>Securities Exchange Act Reports</u>  | 10          |
| <u>ITEM 1A. Risk Factors</u>  | 10          |
| <u>ITEM 1B. Unresolved Staff Comments</u>   | 22          |
| <u>ITEM 2. Properties</u>   | 22          |
| <u>ITEM 3. Legal Proceedings</u>  | 23          |
| <u>ITEM 4. Submission of Matters to a Vote of Security Holders</u>  | 24          |
| <u><b>PART II</b></u>   |             |
| <u>ITEM 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u> | 25          |
| <u>ITEM 6. Selected Financial Data</u>  | 26          |
| <u>ITEM 7. Management's Discussion and Analysis of Results of Operations and Financial Condition</u>                        | 27          |
| <u>ITEM 7A. Quantitative and Qualitative Disclosures about Market Risk</u>  | 37          |
| <u>ITEM 8. Financial Statements and Supplementary Data</u>  | 39          |
| <u>ITEM 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</u>                         | 66          |
| <u>ITEM 9A. Controls and Procedures</u>   | 66          |
| <u>ITEM 9B. Other Information</u>   | 67          |
| <u><b>PART III</b></u>  |             |
| <u>ITEM 10. Directors and Executive Officers of the Registrant</u>  | 67          |
| <u>ITEM 11. Executive Compensation</u>  | 67          |
| <u>ITEM 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>              | 67          |
| <u>ITEM 13. Certain Relationships and Related Transactions</u>  | 67          |
| <u>ITEM 14. Principal Accounting Fees and Services</u>  | 67          |
| <u><b>PART IV</b></u>   |             |
| <u>ITEM 15. Exhibits and Financial Statement Schedules</u>  | 67          |
| <u>Signatures</u>   | 72          |
| <u>EX-10.4.D</u>  |             |
| <u>EX-10.4.E</u>  |             |
| <u>EX-10.5</u>  |             |

[EX-10.6.B](#)  
[EX-10.7.B](#)  
[EX-10.8.B](#)  
[EX-10.9.B](#)  
[EX-10.10.B](#)  
[EX-10.11.B](#)  
[EX-10.12.B](#)  
[EX-10.13.B](#)  
[EX-10.14.B](#)  
[EX-10.15.B](#)  
[EX-10.19.C](#)  
[EX-10.20.C](#)  
[EX-10.21.C](#)  
[EX-10.22.C](#)  
[EX-10.23](#)  
[EX-10.24.B](#)  
[EX-21](#)  
[EX-23](#)  
[EX-31.1](#)  
[EX-31.2](#)  
[EX-32](#)

**Table of Contents**

**PART I**

**ITEM 1. Business**

Mylan Laboratories Inc. (the Company, Mylan Labs, Mylan or we) is engaged in developing, licensing, manufacturing, marketing and distributing generic, brand and branded generic pharmaceutical products. The Company was incorporated in Pennsylvania in 1970. References herein to a fiscal year shall mean the twelve months ended March 31.

**Overview of Our Business**

Prescription pharmaceutical products in the United States ( 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 Abbreviated New Drug Application ( 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 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.

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 who is entitled to the 180 day exclusivity period described above or who 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

**Table of Contents**

period, and, exclusivity aside, could significantly lower the price at which the generic company could otherwise sell their product upon launch.

We have attained a position of leadership in the generic industry through our ability to obtain ANDA approvals, our uncompromising quality control and our devotion to customer service. We continue to bolster our traditional solid oral dose products with unit dose, transdermal and extended release products. We have entered into strategic alliances with several pharmaceutical companies through product development, distribution and licensing agreements that provide us with additional opportunities to broaden our product line.

We operate through three principal business units, Mylan Pharmaceuticals Inc. ( MPI ), UDL Laboratories, Inc. ( UDL ) and Mylan Technologies Inc. ( Mylan Tech ), all of which are wholly owned subsidiaries of Mylan. 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 Tech. UDL packages and markets products, either obtained from MPI or purchased from third parties, in unit dose formats, for use primarily in hospitals and other institutions.

During the first quarter of fiscal 2006, Mylan announced that it was closing Mylan Bertek Pharmaceuticals Inc. ( Mylan Bertek ), its branded subsidiary, and transferring the responsibility for marketing Mylan Bertek's products to other Mylan subsidiaries. Mylan previously reported its financial results in two reportable segments, Generic and Brand. With the closure of Mylan Bertek, Mylan now reports one segment, and began reporting as such effective with the first quarter of fiscal 2006. 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 and reported as one segment.

Mylan manufactures over 92% of all doses it sells. Our product portfolio includes approximately 150 pharmaceutical products, of which approximately 140 are in capsule or tablet form in an aggregate of approximately 345 dosage strengths. This includes 12 extended release products in 21 dosage strengths. Additionally, we market four transdermal patches in 18 dosage strengths. In addition to those products manufactured by Mylan, we market 75 generic products in 128 dosage strengths under supply and distribution agreements with other pharmaceutical companies. As of December 31, 2005, Mylan held the first or second market position in new and refilled prescriptions dispensed among all pharmaceutical companies in the U.S. with respect to approximately 75% of the generic pharmaceutical products we marketed, excluding unit-dose products.

Approximately 17%, 18% and 17% of net revenues in fiscal years 2006, 2005 and 2004, respectively, were contributed by calcium channel blockers, primarily nifedipine. Additionally, approximately 15% of net revenues in fiscal 2006 were contributed by narcotic agonist analgesics, primarily fentanyl.

On November 24, 2005, we announced the sale of the U.S. and Canadian rights for Apokyn<sup>®</sup> to Vernalis plc. Under the terms of the agreement, Mylan received a cash payment of \$23.0 million. In addition, Mylan will perform certain transitional services for one year, including supply chain management and customer service assistance.

On January 11, 2006, we announced an agreement with Forest Laboratories Holdings, Ltd. ( Forest ), a wholly owned subsidiary of Forest Laboratories, Inc., for the commercialization, development and distribution of Mylan's nebivolol compound in the United States and Canada. Nebivolol, which we licensed in fiscal 2001, is a beta blocker for which we submitted an NDA for the indication of hypertension in April 2004 and which was granted approvable status by the FDA in May 2005. Under the terms of the agreement, Mylan received an up-front payment of \$75.0 million, which will be deferred until the commercial launch of the product. Mylan also has the potential to earn future milestone payments as well as royalties based on nebivolol sales. Upon commercial launch the up-front payment will be amortized into revenue over the remaining term of the license agreement. Forest will pay for future nebivolol development programs and will be responsible for all sales and marketing expenses. Mylan has retained an option to co-promote the product in the future.

Also on January 11, 2006, we announced that Mylan Tech signed two strategic agreements with Cephalon, Inc. to utilize Mylan Tech's innovative transdermal technology to address certain pain and central





## **Table of Contents**

nervous system disorders. Under the terms of the agreements, Mylan and Cephalon will collaborate with the intent to create, develop and commercialize branded transdermal products in exchange for the payment to Mylan Tech of milestones and ongoing royalties based on net sales of the products.

On February 28, 2006, Bristol-Myers Squibb Company ( BMS ) and Somerset Pharmaceuticals, Inc. ( Somerset ), our 50% owned joint venture between Mylan and Watson Pharmaceuticals, Inc., announced that the FDA approved EMSAM® (selegiline transdermal system), the first transdermal patch for the treatment of major depressive disorder. In the prior fiscal year, Somerset entered into an agreement with BMS for the commercialization and distribution of EMSAM. EMSAM patches are manufactured by Mylan Tech. The product was launched in early fiscal 2007.

The future success of our generic products is partially dependent upon continued increasing market acceptance of generic products as substitutes for existing products. Additionally, we expect that our future growth will result from continuously launching new products, including an emphasis on the development or acquisition of new products that may attain FDA first-to-file status, as well as the pursuit of products that are difficult to formulate or for which the active pharmaceutical ingredient is difficult to obtain. For our branded products, growth will be driven through internal development of unique and innovative products and by our ability, through continued marketing efforts, to increase prescriptions for our current products. In addition, for generic and branded products or branded generic products, we intend to continue to seek complementary strategic acquisitions of companies as well as products.

### **Product Development**

Research and development efforts are conducted primarily to enable us to develop, manufacture and market FDA-approved pharmaceuticals in accordance with FDA regulations. Research and development expenses were \$102.1 million, \$87.9 million and \$100.8 million in fiscal 2006, 2005 and 2004, respectively. Our research and development strategy may include the following areas:

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

- development of NDA and ANDA transdermal and polymer film products;

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

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

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

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

- completion of additional preclinical and clinical studies for approved NDA products required by the FDA, known as post-approval (Phase IV) commitments; and

- conducting of life cycle management studies intended to further define the profile of products subject to pending or approved NDAs.

All applications for FDA approval must contain information relating to product formulation, raw material suppliers, stability, manufacturing processes, packaging, labeling and quality control. Information to support the bioequivalence of generic drug products or the safety and effectiveness of new drug products for their intended use is also required to be submitted. There are generally two types of applications used for obtaining FDA approval of new products:

*New Drug Application ( NDA )*. An NDA is filed when approval is sought to market a drug with active ingredients that have not been previously approved by the FDA. NDAs are filed for newly developed brand products and, in certain instances, for a new dosage form, a new delivery system, or a new indication for previously approved

drugs.

## **Table of Contents**

*Abbreviated New Drug Application ( 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.

### **Generic Product Development**

FDA approval of an ANDA is required before marketing a generic equivalent of a drug approved under an NDA 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.

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.

During fiscal 2006, Mylan received 16 application approvals from the FDA, consisting of 11 final ANDA approvals, four tentative ANDA approvals and one supplemental ANDA approval for a new product strength. This ability to succeed in obtaining new product approvals has been made possible by Mylan's continued commitment to, and investment in, research and development and legal costs in the form of patent challenges.

As of March 31, 2006, Mylan had 56 ANDAs and five supplemental ANDAs for new product strengths pending FDA approval, which represent products with calendar year 2005 brand sales of approximately \$47.0 billion. Of these 61 applications, 17 have been granted tentative approval/approvable status and represent approximately \$20.0 billion in calendar year 2005 brand sales. Because generic products have selling prices which are generally lower than their branded counterparts, sales of generic products will not generate the same level of net revenues as sales of an equivalent number of units of branded products.

A large number of high-value branded pharmaceutical patent expirations are expected over the next five years. The current estimated U.S. annual brand sales for such products are approximately \$72.0 billion. These patent expirations should provide additional generic product opportunities. We intend to concentrate our generic product development activities on brand products with significant U.S. 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.

### **Brand Product Development**

The process required by the FDA before a previously unapproved pharmaceutical product may be marketed in the U.S. generally involves the following:

laboratory and preclinical tests;

submission of an Investigational New Drug ( IND ) application, which must become effective before clinical studies may begin;

## **Table of Contents**

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

Human clinical studies are typically conducted in three sequential phases:

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 10 years.

### **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. Following patent expiration, brand products often continue to have market viability based upon the goodwill of the product name, which typically benefits from trademark protection. 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.

### **Customers and Marketing**

We market our generic products directly to wholesalers, distributors, retail pharmacy chains, mail order pharmacies, group purchasing organizations and others within the U.S. We also market our generic products indirectly to independent pharmacies, managed care organizations, hospitals, nursing homes, pharmacy

## **Table of Contents**

benefit management companies and government entities. These customers, called indirect customers, purchase our products primarily through our wholesale 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 discussion of all of our revenue provisions.

Sales of products to AmerisourceBergen Corporation, Cardinal Health, Inc. and McKesson Corporation represented approximately 16%, 14% and 17%, respectively, of net revenues in fiscal 2006. Sales of products to AmerisourceBergen Corporation, Cardinal Health, Inc. and McKesson Corporation represented approximately 11%, 19% and 16%, respectively, of net revenues in fiscal 2005. Sales of products to Cardinal Health, Inc. and McKesson Corporation represented approximately 21% and 15%, respectively, of net revenues in fiscal 2004.

### **Competition**

The pharmaceutical industry is very competitive. Our competitors vary depending upon therapeutic 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 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 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 developing generic therapeutic equivalents to brand products that offer unique marketing opportunities and developing or licensing brand pharmaceutical products that are either patented or proprietary and that are primarily for indications having relatively large patient populations or that have limited or inadequate treatments available.

### **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.

Currently, 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. For the current policy period, which began on September 30, 2005 and ends on September 30, 2006, we are self-insured for certain coverage relating to product liability claims including the first \$10.0 million of costs incurred.

### **Raw Materials**

The active pharmaceutical ingredients and other materials and supplies used in our pharmaceutical manufacturing operations are generally available and purchased from many different foreign and domestic suppliers. However, in some cases, the raw materials used to manufacture pharmaceutical products are available only from a single FDA-approved 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

**Table of Contents**

change in a supplier not previously approved must then be submitted through a formal approval process with the FDA.

**Government Regulation**

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 Waxman-Hatch Act, the Generic Drug Enforcement Act, and other federal government statutes and regulations govern or influence the testing, manufacturing, packaging, labeling, storing, recordkeeping, safety, approval, advertising, promotion, sale and distribution of products.

FDA approval is required before any new drug can be marketed. The FDA requires extensive testing of new pharmaceutical products to demonstrate that such products are both safe and effective in treating the indications for which approval is sought. Testing in humans may not be commenced until after an IND exemption is granted by the FDA. An NDA or supplemental NDA must be submitted to the FDA both for new drugs that have not been previously approved by the FDA and for new combinations of, new indications for or new delivery methods for previously approved drugs.

FDA approval of an ANDA is required before a generic equivalent of an existing or referenced brand drug can be marketed. The ANDA process is abbreviated in that the FDA waives the requirement of conducting complete preclinical and clinical studies and, instead, relies on bioequivalence studies.

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 within 45 days of notification by the applicant, the FDA may not approve the ANDA application until the earlier of a court decision favorable to the ANDA applicant has been rendered 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.

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 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 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.

**Table of Contents**

Under Part D of the Medicare Modernization Act, beginning January 1, 2006, Medicare beneficiaries are eligible to obtain discounted prescription drug coverage from private sector providers. It is difficult to predict the impact the Medicare prescription drug coverage benefit will have on pharmaceutical companies. Usage of pharmaceuticals may increase as a result of the expanded access to medicines afforded by the new Medicare prescription drug benefit. However, such potential sales increases may be offset by increased pricing pressures due to the enhanced purchasing power of the private sector providers who are negotiating on behalf of Medicare beneficiaries.

**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 employ approximately 2,900 persons, approximately 900 of whom serve in clerical, sales and management capacities. The remaining employees are engaged in production and maintenance activities.

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, 2007.

**Backlog**

At May 4, 2006, open orders were approximately \$61.3 million. Because of the relatively short lead time required in filling orders for our products, we do not believe these backlog amounts bear a significant relationship to sales or income for any full 12-month period.

**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 Annual Report on Form 10-K and shall not be deemed filed under the Securities Exchange Act of 1934.

**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.

**Table of Contents**

**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 (usually brand) 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 the products that we are developing or licensing (including, without limitation, nebivolol) on a timely basis, if at all, which could adversely affect our product introduction plans, financial position and results of operations and could cause the market value of our common stock to decline.

FDA approval is required before any prescription drug product, including generic drug products, can be marketed. The process of obtaining FDA approval to manufacture and market new and generic pharmaceutical products is rigorous, time-consuming, costly and largely unpredictable. We, or a partner, may be unable to obtain requisite FDA approvals on a timely basis for new generic or brand products that we may develop, license or otherwise acquire. 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 FDA approval is denied or delayed we could be exposed to the risk of this inventory becoming obsolete. The timing and cost of obtaining FDA approvals could adversely affect our product introduction plans, financial position and results of operations and could cause the market value of our common stock to decline.

The ANDA approval process often results in the FDA granting final approval to a number of ANDAs for a given product at the time a patent claim for a corresponding brand product or other market exclusivity expires. This often forces us to face immediate competition when we introduce a generic product into the market. Additionally, ANDA 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 brand products. New generic market entrants generally cause continued price and margin erosion over the generic product life cycle.

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, it generally results in higher market share, net revenues and gross margin for that applicant. 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 financial position and results of operations, and the market value of our common stock could decline.



**Table of Contents**

**OUR APPROVED PRODUCTS MAY NOT ACHIEVE EXPECTED LEVELS OF MARKET ACCEPTANCE, WHICH COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR PROFITABILITY, 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 brand, 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. Our new products may not achieve expected levels of market acceptance. 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. For example, on July 15, 2005, the FDA issued a Public Health Advisory regarding the safe use of transdermal fentanyl patches, a product we currently market, the loss of revenues of which could have a significant impact on our business. In some cases, studies have resulted, and may in the future result, in the discontinuance of product marketing. These situations, should they occur, could have a material adverse effect on our profitability, financial position and results of operations, and the market value of our common stock could decline.

**A RELATIVELY SMALL GROUP OF PRODUCTS MAY REPRESENT A SIGNIFICANT PORTION OF OUR 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, WHICH COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS, FINANCIAL POSITION AND RESULTS OF OPERATIONS AND COULD CAUSE THE MARKET VALUE OF OUR COMMON STOCK TO DECLINE.**

Our competitors 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;



**Table of Contents**

more products; or

more experience in developing new drugs and financial resources, particularly with regard to brand manufacturers.

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 federal and state governmental authorities. For instance, we must comply with FDA requirements with respect to the manufacture, labeling, sale, distribution, marketing, advertising, promotion and development of pharmaceutical products. Failure to comply with FDA and other governmental regulations 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 FDA's review of NDAs or ANDAs, enforcement actions, injunctions and criminal prosecution. Under certain circumstances, the FDA also has 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 addition to the new drug approval process, the FDA also regulates the facilities and operational procedures that we use to manufacture our products. We must register our facilities with the FDA. All products manufactured in those facilities must be made in a manner consistent with current good manufacturing practices ( 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 periodically inspects our manufacturing facilities for compliance. FDA 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 which could include withholding the approval of NDAs, ANDAs or other product applications of that facility. If the FDA 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 approval to manufacture at a different facility also could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

We are subject, as are generally all manufacturers, to various federal, state and local laws regulating working conditions, as well as environmental protection laws and regulations, including those governing the discharge of materials into the environment. 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.

**Table of Contents**

**OUR REPORTING AND PAYMENT OBLIGATIONS UNDER THE MEDICAID REBATE PROGRAM AND OTHER GOVERNMENTAL PURCHASING AND REBATE PROGRAMS ARE COMPLEX AND MAY INVOLVE SUBJECTIVE DECISIONS. 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 Medicaid reimbursement and rebates and other governmental programs are complex, and 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 U.S. Department of Justice with respect to Medicaid reimbursement and rebates. Our calculations and methodologies are currently being reviewed internally and likewise are subject to review and challenge by the applicable governmental agencies, and it is possible that such reviews could result in material changes. In addition, 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, as also disclosed in this Form 10-K, a number of state and federal government agencies are conducting investigations of manufacturers' reporting practices with respect to Average Wholesale Prices (AWP), in which they have suggested that reporting of inflated AWP has led to excessive payments for prescription drugs. We and numerous other pharmaceutical companies have been named as defendants in various actions relating to pharmaceutical pricing issues and whether allegedly improper actions by pharmaceutical manufacturers led to excessive payments by Medicare and/or Medicaid.

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

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

Much of our development effort is focused on technically difficult-to-formulate products and/or products that require advanced manufacturing technology. We conduct research and development primarily to enable us to manufacture and market FDA-approved pharmaceuticals in accordance with FDA regulations. Typically, research expenses related to the development of innovative compounds and the filing of NDAs are significantly greater than those expenses associated with ANDAs. 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, nebivolol), our, or a partner's, research and development expenditures may not result in the successful introduction of FDA approved new pharmaceutical products. Also, after we submit an NDA or ANDA, the FDA 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,



**Table of Contents**

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

A significant portion of our net revenues are derived from sales to a limited number of customers. As such, a reduction in or loss of business with one customer, or if one 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 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 brand and generic, often pursue strategies to prevent or delay competition from generic alternatives to brand 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, including timing the filings so as to thwart generic competition by causing delays of our product approvals;

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

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

filing suits for patent infringement that automatically delay FDA 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 FDA approval;

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

persuading the FDA 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.

The Food and Drug Modernization Act of 1997 includes a pediatric exclusivity provision that may provide an additional six months of market exclusivity for indications of new or currently marketed drugs if certain agreed upon pediatric studies are completed by the applicant. Brand companies are utilizing this provision to extend periods of

market exclusivity.

**Table of Contents**

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 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.

**THE INDENTURE FOR OUR SENIOR NOTES AND OUR SENIOR SECURED CREDIT FACILITY IMPOSE SIGNIFICANT OPERATING AND FINANCIAL RESTRICTIONS, WHICH MAY PREVENT US FROM CAPITALIZING ON BUSINESS OPPORTUNITIES AND TAKING SOME ACTIONS. THESE FACTORS COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS, FINANCIAL POSITION AND RESULTS OF OPERATIONS AND COULD CAUSE THE MARKET VALUE OF OUR COMMON STOCK TO DECLINE.**

The indenture for our Senior Notes and senior secured credit facility impose significant operating and financial restrictions on us. These restrictions will limit the ability of us and our subsidiaries to, among other things, incur additional indebtedness, make investments, sell assets, incur certain liens, enter into agreements restricting our subsidiaries' ability to pay dividends, or merge or consolidate. In addition, our senior secured credit facility 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 the indebtedness, together with accrued interest and other fees, to be immediately due and payable and proceed against any collateral securing that indebtedness. 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 ABILITY TO SERVICE OUR DEBT AND MEET OUR CASH REQUIREMENTS DEPENDS ON MANY FACTORS, SOME OF WHICH ARE BEYOND OUR CONTROL. 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 ability to satisfy our obligations, including our Senior Notes and our senior secured credit facility, will depend on our future operating performance and financial results, which will be subject, in part, to factors beyond our control, including interest rates and general economic, financial and business conditions. If we are unable to generate sufficient cash flow, we may be required to: refinance all or a portion of our debt, including the notes and our senior secured credit facility; obtain additional financing in the future for acquisitions, working capital, capital expenditures and general corporate or other purposes; redirect a substantial portion of our cash flow to debt service, which as a result, might not be available for our operations or other purposes; sell some of our assets or operations; reduce or delay capital expenditures; or revise or delay our operations or strategic plans. If we are required to take any of these actions, it could have a material adverse effect on our business, financial condition or results of operations. In addition, we cannot assure you that we would be able to take any of these actions, that these actions would enable us to continue to satisfy our capital requirements or that these actions would be permitted under the terms of our senior secured credit facility and the indenture governing the notes. The increased leverage resulting from the financing of our Dutch Auction self-tender offer through our notes offering and our senior secured credit facility could have certain material adverse effects on us, including limiting our ability to obtain additional financing and reducing cash available for our operations and acquisitions. As a result, our ability to withstand competitive pressures may be decreased and, we may be more vulnerable to economic downturns, which in turn could reduce our flexibility in responding to changing business, regulatory and economic conditions. These factors could have a material adverse effect on





**Table of Contents**

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

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

We typically purchase the active pharmaceutical ingredient (i.e. the chemical compounds that produce the desired therapeutic effect in our products) and other materials and supplies that we use in our manufacturing operations, as well as certain finished products, from many different 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 the FDA, have received FDA 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.

The Company utilizes controlled substances in certain of its current products and products in development and therefore must meet the requirements of the Controlled Substances Act of 1970 and the related regulations administered by the Drug Enforcement Administration ( DEA ). These regulations relate to the manufacture, shipment, storage, sale and use of controlled substances. The DEA limits 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 for procurement quota in order to obtain these substances. Any delay or refusal by the DEA in establishing our procurement quota for controlled substances could delay or stop our clinical trials or product launches, or could cause trade inventory disruptions for those products that have already been launched, which could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

**WE USE SEVERAL MANUFACTURING FACILITIES TO MANUFACTURE OUR PRODUCTS. HOWEVER, A SIGNIFICANT NUMBER OF OUR PRODUCTS ARE PRODUCED AT ONE LOCATION. PRODUCTION AT THIS FACILITY 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.**

Although we have other facilities, we produce a significant number of our products at our largest manufacturing facility. A significant disruption at that facility, 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.

**Table of Contents**

**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.**

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

**WE MAY BE UNABLE TO PROTECT OUR INTELLECTUAL AND OTHER PROPRIETARY PROPERTY IN AN EFFECTIVE MANNER, 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.**

Although our brand products may have patent protection, this may not prevent other companies from developing functionally equivalent products or from challenging the validity or enforceability of our patents. If any patents we use in our business are found or even alleged to be non-infringed, invalid or not enforceable, we could experience an adverse effect on our ability to commercially promote our patented products. We could be required to enforce our patent or other intellectual property rights through litigation, which can be protracted and involve significant expense and an inherently uncertain outcome. Any negative outcome could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

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

Companies that produce brand pharmaceutical products routinely bring litigation against ANDA applicants that seek FDA 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 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.

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 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 brand 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



**Table of Contents**

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 and private health insurers and other organizations, such as HMOs, 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. 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.

**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 or state laws and regulations may influence the prices of drugs and, therefore, could adversely affect the prices that we receive for our products. Programs in existence in certain 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 Medicaid programs, or changes required in the way in which Medicaid rebates are calculated under such programs, could adversely affect the price 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.

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

We are involved in various legal proceedings and certain government inquiries, including, but not limited to, patent infringement, product liability, breach of contract and claims involving Medicaid and Medicare 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 for 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, the Company maintains commercial insurance to protect against and manage a portion of the risks involved in conducting its 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.

**Table of Contents**

**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 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 ACQUISITION STRATEGIES IN GENERAL 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 A DECLINE IN THE MARKET VALUE OF OUR COMMON STOCK.**

We continually seek to expand our product line through complementary or strategic acquisitions of other companies, products and assets, and through joint ventures, licensing agreements or other arrangements. Acquisitions, joint ventures and other business combinations involve various inherent risks, such as assessing accurately the values, strengths, weaknesses, contingent and other liabilities, regulatory compliance and potential profitability of acquisition or other transaction candidates. Other inherent risks include the potential loss of key personnel of an acquired business, our inability to achieve identified financial and operating synergies anticipated to result from an acquisition or other transaction and unanticipated changes in business and economic conditions affecting an acquisition or other transaction. International acquisitions, and other transactions, could also be affected by export controls, exchange rate fluctuations, domestic and foreign political conditions and the deterioration in domestic and foreign economic conditions.

We may be unable to realize synergies or other benefits expected to result from acquisitions, joint ventures and 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, market factors and the deterioration in domestic and global economic conditions could alter the anticipated benefits of any such transactions. These factors could 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.

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

Because our success is largely dependent on the scientific nature of our business, it is imperative 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 all of 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.

**Table of Contents**

**RECENT DECISIONS BY THE FDA, CURRENT BRAND TACTICS AND OTHER FACTORS BEYOND OUR CONTROL HAVE PLACED OUR BUSINESS UNDER INCREASING PRESSURE, 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 believe that certain recent FDA rulings are contrary to multiple sections of the Federal Food, Drug, and Cosmetic Act and the Administrative Procedures Act, the FDA's published regulations and the legal precedent on point. These decisions call into question the rules of engagement in our industry and have added a level of unpredictability that may materially adversely affect our business and the generic industry as a whole. While we continue to challenge these recent decisions as well as current brand tactics that undermine congressional intent, we cannot guarantee that we will prevail or predict when or if these matters will be rectified. If they are not, our business, financial position and results of operations could suffer and the market value of our common stock could 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 ( ERP ) system 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.

**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, including 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 systems, and attestations as to the effectiveness of these systems by our independent registered public accounting firm. If we fail to maintain the adequacy of our internal controls, we may not be able to ensure that we can conclude on an ongoing basis that we have effective internal control over financial reporting. Additionally, internal control over financial reporting may not prevent or detect misstatements because of its inherent limitations, including the possibility of human error, the circumvention or overriding of controls, or fraud. Therefore, even effective internal controls can provide only reasonable assurance with respect to the preparation and fair presentation of financial statements. In addition, projections of any evaluation of effectiveness of internal control over financial reporting to future periods are subject to the risk that the control may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. If the Company fails to maintain the adequacy of its internal controls, including any failure to implement required new or improved controls, this could have a material adverse effect on our business, financial position and results of operations, and the market value of our common stock could decline.

**Table of Contents**

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

The consolidated and condensed consolidated financial statements included in the periodic reports we file with the SEC are prepared in accordance with accounting principles generally accepted in the United States of America ( GAAP ). The preparation of financial statements in accordance with GAAP involves making estimates, judgments and assumptions that affect reported amounts of assets (including intangible assets), liabilities, revenues, expenses 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. Any such changes could result in corresponding changes to the amounts of assets (including goodwill and other intangible assets), liabilities, revenues, expenses and income. Any such changes could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

**ITEM Unresolved Staff Comments****1B.**

None.

**ITEM 2. Properties**

We maintain various facilities in the U.S. and Puerto Rico. These facilities are used for research and development, manufacturing, warehousing, distribution and administrative functions and consist of both owned and leased properties.

The following summarizes the properties used to conduct our operations:

| <b>Location</b> | <b>Status</b> | <b>Primary Use</b>       |
|-----------------|---------------|--------------------------|
| North Carolina  | Owned         | Distribution             |
|                 |               | Warehousing              |
| West Virginia   | Owned         | Manufacturing            |
|                 |               | Warehousing              |
|                 |               | Research and Development |
|                 | Owned         | Administrative           |
|                 | Leased        | Warehousing              |
| Illinois        |               | Administrative           |
|                 | Owned         | Manufacturing            |
|                 |               | Warehousing              |
|                 | Owned         | Administrative           |
|                 | Leased        | Warehousing              |
| Puerto Rico     |               | Manufacturing            |
|                 | Owned         | Warehousing              |
|                 |               | Administrative           |
| Texas           | Owned         | Manufacturing            |
|                 | Owned         | Warehousing              |
| Vermont         |               | Manufacturing            |
|                 | Owned         | Research and Development |
|                 |               | Administrative           |
|                 | Owned         | Warehousing              |



Pennsylvania

Owned

Administrative

**Table of Contents**

All facilities are in good operating condition. The machinery and equipment are well-maintained, and the facilities are suitable for their intended purposes and have capacities adequate for current operations.

**ITEM 3. Legal Proceedings**

While it is not possible to determine with any degree of certainty the ultimate outcome of the following legal proceedings, the Company believes that it has meritorious defenses with respect to the claims asserted against it and intends to vigorously defend its position. 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, MPI filed an ANDA seeking approval from the 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 Labs 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 Labs 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 Labs 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, and a non-jury trial commenced on April 3, 2006.

*Lorazepam and Clorazepate*

On June 1, 2005, a jury verdict was rendered against Mylan Labs and MPI in the U.S. District Court for the District of Columbia (D.C.) in the amount of approximately \$12.0 million, which has been accrued for by the Company. The jury found Mylan willfully violated Massachusetts, Minnesota and Illinois state antitrust laws, meaning the amount of the verdict could be trebled and an award of attorneys' fees and litigation costs could be made to the plaintiffs. 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 claims relating to Mylan's 1998 price increases for lorazepam and clorazepate. The Company filed a motion for judgment as a matter of law, a motion for a new trial and a motion to reduce verdict, all of which remain pending before the court. If the Company's post-verdict motions are denied, the Company intends to appeal to the U.S. Court of Appeals for the D.C. Circuit.

*Pricing and Medicaid Litigation*

On June 26, 2003, MPI and UDL received requests from the U.S. House of Representatives Energy and Commerce 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 are cooperating 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 Labs 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.

**Table of Contents**

Beginning in September 2003, Mylan Labs, 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 Labs, MPI and UDL have been named as defendants in substantially similar civil lawsuits filed by the AGs of Alabama, California, Florida, Illinois, Kentucky, Massachusetts, Mississippi, Missouri 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 Massachusetts and Alabama AG actions discussed below, Mylan Labs and its subsidiaries either have not yet been required to respond to the complaints or have motions to dismiss pending. The Company previously reported that the U.S. District Court for the District of Massachusetts had dismissed the complaint filed by the Massachusetts AG without prejudice and with leave to amend. The Massachusetts AG since filed an amended complaint which survived motions to dismiss, and Mylan Labs answered on November 14, 2005, denying liability. In addition, the Alabama AG filed a second amended complaint which has survived motions to dismiss, and Mylan Labs, MPI and UDL answered on January 30, 2006, denying liability. Lastly, we have been advised that Mylan Labs and MPI have been included as defendants in an AWP complaint filed by the state of Hawaii. Neither entity, however, has been served with a complaint in that action. Mylan Labs 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. To the best of MPI s information, the investigation is in its early stages. MPI is collecting information requested by the government and is cooperating fully with the government s investigation.

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

Our common stock is traded on the 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>Fiscal 2006</b> | <b>High</b> | <b>Low</b> |
|--------------------|-------------|------------|
| First quarter      | \$ 20.03    | \$ 15.21   |
| Second quarter     | 20.00       | 17.19      |
| Third quarter      | 21.69       | 18.29      |
| Fourth quarter     | 25.00       | 19.05      |

  

| <b>Fiscal 2005</b> | <b>High</b> | <b>Low</b> |
|--------------------|-------------|------------|
| First quarter      | \$ 24.95    | \$ 19.80   |
| Second quarter     | 20.65       | 14.24      |
| Third quarter      | 20.00       | 16.24      |
| Fourth quarter     | 18.19       | 15.50      |

As of May 1, 2006, there were approximately 137,300 holders of record of our common stock, including those held in street or nominee name.

In the third quarter of fiscal 2004, the Company's Board of Directors voted to increase the quarterly dividend by 35% to 3.0 cents per share. During the first quarter of fiscal 2006, the Company's Board of Directors voted to double the quarterly dividend to 6.0 cents per share, effective with the dividend paid for the first quarter of fiscal 2006. We currently expect to continue the practice of paying regular cash dividends.

Information regarding the Company's equity compensation plans is incorporated by reference into ITEM 12 in Part III of this Form 10-K.

During the quarter ended March 31, 2006, the Company repurchased 1,805,600 shares of common stock as follows:

| <b>Period</b>                        | <b>Total Number of Shares Purchased</b> | <b>Average Price Paid per Share</b> | <b>Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs</b> | <b>Approximate Dollar Value of Shares that May Yet Be Purchased Under the Program</b> |
|--------------------------------------|---|-------------------------------------|---|---|
| January 1, 2006 - January 31, 2006   |   |                                     |   | \$ 39,447,565   |
| February 1, 2006 - February 28, 2006 | 1,805,600                               | \$ 21.85                            | 1,805,600 <sup>(1)</sup>  |   |
| March 1, 2006 - March 31, 2006       |   |                                     |   |   |

<sup>(1)</sup> On June 14, 2005, in connection with the announcement of a modified Dutch Auction self-tender for up to \$1.0 billion, which commenced on June 16, 2005 and closed on July 21, 2005, Mylan also announced a

\$250.0 million follow-on share repurchase program in the open market or otherwise. The follow-on share repurchase program was completed on February 14, 2006.

**Table of Contents****ITEM 6. Selected Financial Data**

The selected consolidated financial data set forth below should be read in conjunction with Management's Discussion and Analysis of Results of Operations and Financial Condition and the Consolidated Financial Statements and related Notes to Consolidated Financial Statements included elsewhere in this Annual Report on Form 10-K.

| <b>Fiscal Year Ended March 31,</b>  | <b>2006</b>  | <b>2005</b>  | <b>2004</b>  | <b>2003</b>  | <b>2002</b>  |
|-------------------------------------|--------------|--------------|--------------|--------------|--------------|
| <b>Statements of Earnings:</b>      |              |              |              |              |              |
| Total revenues                      | \$ 1,257,164 | \$ 1,253,374 | \$ 1,374,617 | \$ 1,269,192 | \$ 1,104,050 |
| Cost of sales                       | 629,548      | 629,834      | 612,149      | 597,756      | 480,111      |
| Gross profit                        | 627,616      | 623,540      | 762,468      | 671,436      | 623,939      |
| <b>Operating expenses:</b>          |              |              |              |              |              |
| Research and development            | 102,057      | 87,881       | 100,813      | 86,748       | 58,847       |
| Selling, general and administrative | 225,754      | 259,478      | 201,612      | 173,070      | 169,913      |
| Litigation settlements, net         | 12,417       | (25,990)     | (34,758)     | (2,370)      |              |
| Earnings from operations            | 287,388      | 302,171      | 494,801      | 413,988      | 395,179      |
| Interest expense                    | 31,285       |              |              |              |              |
| Other income, net                   | 18,502       | 10,076       | 17,807       | 12,525       | 13,144       |
| Earnings before income taxes        | 274,605      | 312,247      | 512,608      | 426,513      | 408,323      |
| Provision for income taxes          | 90,063       | 108,655      | 177,999      | 154,160      | 148,072      |
| Net earnings                        | \$ 184,542   | \$ 203,592   | \$ 334,609   | \$ 272,353   | \$ 260,251   |

| <b>March 31,</b>                                   | <b>2006</b>  | <b>2005</b>  | <b>2004</b>  | <b>2003</b>  | <b>2002</b>  |
|--|--------------|--------------|--------------|--------------|--------------|
| <b>Selected balance sheet data:</b>                |              |              |              |              |              |
| Total assets                                       | \$ 1,870,526 | \$ 2,135,673 | \$ 1,885,061 | \$ 1,745,223 | \$ 1,619,880 |
| Working capital                                    | 926,650      | 1,282,945    | 1,144,073    | 962,440      | 891,598      |
| Deferred revenue                                   | 89,417       |              |              |              |              |
| Long-term obligations                              | 22,435       | 19,325       | 19,130       | 19,943       | 23,883       |
| Long-term debt                                     | 685,188      |              |              |              |              |
| Total shareholders' equity                         | 787,651      | 1,845,936    | 1,659,788    | 1,446,332    | 1,402,239    |
| <b>Per common share data:</b>                      |              |              |              |              |              |
| <b>Net earnings</b>                                |              |              |              |              |              |
| Basic  | \$ 0.80      | \$ 0.76      | \$ 1.24      | \$ 0.98      | \$ 0.92      |
| Diluted  | \$ 0.79      | \$ 0.74      | \$ 1.21      | \$ 0.96      | \$ 0.91      |
| Shareholders' equity diluted                       | \$ 3.36      | \$ 6.75      | \$ 6.01      | \$ 5.12      | \$ 4.89      |
| Cash dividends declared and paid                   | \$ 0.24      | \$ 0.12      | \$ 0.10      | \$ 0.08      | \$ 0.07      |
| <b>Weighted average common shares outstanding:</b> |              |              |              |              |              |
| Basic  | 229,389      | 268,985      | 268,931      | 278,789      | 282,432      |
| Diluted  | 234,209      | 273,621      | 276,318      | 282,330      | 286,578      |



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

The following discussion and analysis, as well as other sections in this Annual Report, should be read in conjunction with the Consolidated Financial Statements and related Notes to Consolidated Financial Statements included elsewhere in this report. All references to fiscal years shall mean the 12-month period ended March 31.

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 date of this Form 10-K.

**Overview**

Mylan Laboratories Inc. and its subsidiaries (the Company, Mylan or we) develop, license, manufacture, market and distribute generic, brand and branded generic pharmaceutical products. Net revenues for fiscal 2006 were \$1.24 billion compared to fiscal 2005 revenues of \$1.25 billion.

Consolidated gross profit for fiscal 2006 was \$627.6 million compared to \$623.5 million in the prior year, an increase of 1%, while gross margins were consistent at approximately 50%. Net earnings for fiscal 2006 were \$184.5 million compared to \$203.6 million in fiscal 2005, a decrease of \$19.0 million or 9%. In the same period, however, earnings per diluted share increased from \$0.74 in fiscal 2005 to \$0.79 in fiscal 2006. Current year earnings per share were impacted by share buybacks, including a modified Dutch Auction self-tender, which closed on July 21, 2005, whereby the Company accepted for payment an aggregate of 51,282,051 shares of its common stock at a purchase price of \$19.50 per share. See below for further discussion.

Additionally, included in the current year results are expenses in the amount of \$0.04 per diluted share, net of tax, with respect to a contingent legal liability related to previously disclosed litigation in connection with the Company's lorazepam and clorazepate products and \$0.06 per diluted share, net of tax, of restructuring costs. Included in the financial results for fiscal 2005 were \$0.06 per diluted share, net of tax, of income from the favorable settlement of other litigation.

A more thorough discussion of operating results is provided under the section Results of Operations.

Other factors which impacted the results of fiscal 2006 were:

**Nebivolol Licensing Agreement** On January 11, 2006, the Company announced an agreement with Forest Laboratories Holdings, Ltd. (Forest), a wholly owned subsidiary of Forest Laboratories, Inc., for the commercialization, development and distribution of Mylan's beta blocker, nebivolol, in the United States (U.S.) and Canada. Under the terms of the agreement, Mylan received an up-front payment of \$75.0 million, which will be deferred until the commercial launch of the product. Mylan also has the potential to earn future milestone payments as well as royalties based on nebivolol sales. Upon commercial launch, the up-front payment will be amortized into revenue over the remaining term of the license agreement. Forest has assumed all expenses for future nebivolol development programs and will be responsible for all sales and marketing expenses. Mylan has retained an option to co-promote the product in the future.

**EMSAM® Approval** On February 28, 2006, Bristol-Myers Squibb Company (BMS) and Somerset Pharmaceuticals, Inc. (Somerset), a joint venture between Mylan and Watson Pharmaceuticals, Inc., announced that the FDA approved EMSAM (selegiline transdermal system),



**Table of Contents**

the first transdermal patch for the treatment of major depressive disorder. In the prior fiscal year, Somerset entered into an agreement with BMS for the commercialization and distribution of EMSAM. EMSAM patches are manufactured by Mylan Technologies Inc., a subsidiary of Mylan. The product was launched in early fiscal 2007.

**Oxybutynin Agreements** On December 20, 2005, Mylan announced that Mylan Pharmaceuticals Inc. ( MPI ) entered into two agreements with Ortho-McNeil Pharmaceutical, Inc. and Alza Corporation relating to oxybutynin chloride extended-release tablets, the generic equivalent of Ditropan XL. Under these agreements, an exclusive supply agreement on all strengths of oxybutynin will be triggered upon a final appellate court decision in the current patent litigation between the parties. Ortho-McNeil has also agreed to supply Mylan with a generic version of Ditropan XL sooner than a final appellate court decision if another generic version enters the market. Additionally, Mylan will be granted a non-exclusive, royalty bearing license to make and sell its ANDA products. The terms of these agreements differ depending upon the final outcome of the pending patent litigation. The terms of the agreements are confidential and subject to a number of conditions, including review by the U.S. Federal Trade Commission. Mylan has received tentative approval and is currently awaiting final approval from the FDA for its 5 mg and 10 mg strengths of oxybutynin. Prior to a final appellate court decision, Mylan retains all of the options that had been available to it with respect to oxybutynin prior to the signing of these agreements.

**Sale of Apokyn®** On November 24, 2005, the Company announced the sale of the U.S. and Canadian rights for Apokyn to Vernalis plc. Under the terms of the agreement, Mylan received a cash payment of \$23.0 million. In addition, Mylan will perform certain transitional services for one year, including supply chain management and customer service assistance. During fiscal 2006, \$8.9 million of revenue associated with the sale was recognized and included in other revenues. The remainder, net of certain related assets, has been recorded as deferred revenue and is being recognized over the one-year period.

**Share Buyback** On July 21, 2005, Mylan closed on its modified Dutch Auction self-tender and accepted for payment an aggregate purchase price of approximately \$1.0 billion, 51,282,051 shares of its common stock at a price of \$19.50 per share.

Subsequent to the completion of the Dutch Auction self-tender, Mylan completed a previously announced open market follow-on repurchase by repurchasing 12,595,200 shares of its common stock on the open market for an aggregate purchase price of approximately \$250.0 million.

**Financing** The share buyback described above was financed through Mylan's existing cash reserves as well as \$500.0 million in Senior Notes and a \$275.0 million borrowing under a \$500.0 million senior secured credit facility. The Senior Notes, which were issued on July 21, 2005, consist of \$150.0 million of Senior Notes due 2010, and bearing interest at 5<sup>3</sup>/<sub>4</sub>% per annum, and \$350.0 million of Senior Notes due 2015, and bearing interest at 6<sup>3</sup>/<sub>8</sub> % per annum. The senior secured credit facility, which was also entered into on July 21, 2005, consists of a \$225.0 million five-year revolving credit facility, which the Company expects to use for working capital and general corporate purposes, and a \$275.0 million five-year term loan. The term loan bears interest at LIBOR plus 150 basis points or prime plus 50 basis points at the Company's option. The interest rate in effect on the term loan at March 31, 2006, was 6.33%. At March 31, 2006, \$188.0 million was outstanding under the term loan and no borrowings were outstanding under the revolving credit facility.

**Closure of Mylan Bertek** During the first quarter of fiscal 2006, Mylan announced that it was closing Mylan Bertek Pharmaceuticals Inc. ( Mylan Bertek ), its branded subsidiary, and transferring responsibility for selling Mylan Bertek's products to its other subsidiaries, MPI and UDL Laboratories, Inc. In connection with this restructuring, the Company incurred restructuring charges of \$20.9 million, of which \$19.9 million was included in selling, general and administrative ( SG&A ) expense. The restructuring charge consisted primarily of employee termination and severance costs associated with the Mylan Bertek sales force, along with lease termination costs

and asset write-downs. As of March 31, 2006, the restructuring was substantially completed.

**Table of Contents****Results of Operations****Fiscal 2006 Compared to Fiscal 2005***Total Revenues and Gross Profit*

Net revenues for fiscal 2006 were \$1.24 billion compared to \$1.25 billion for fiscal 2005, a decrease of \$7.8 million or 1%. 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 fiscal year ended March 31, 2006, the most significant amounts charged against gross revenues were for chargebacks in the amount of \$1.11 billion and customer performance and promotions in the amount of \$160.8 million. For fiscal 2005, chargebacks of \$892.6 million and customer performance and promotions of \$195.1 million were charged against gross revenues. The increase in the amounts charged against gross revenues for chargebacks in the current year is the result of pricing pressures on certain products in the Company's portfolio, most notably omeprazole and carbidopa/levodopa, a full year of chargebacks related to fentanyl and an increase in sales to customers who are entitled to chargeback credits. Customer performance and promotions include direct rebates as well as promotional programs. A greater amount was charged against gross revenues for customer performance and promotions in fiscal 2005, primarily due to promotions offered to customers in connection with the launch of fentanyl that occurred in the fourth quarter of the prior fiscal year.

New products launched during the year contributed \$6.7 million to net revenues in fiscal 2006 compared to \$87.3 million in fiscal 2005, primarily due to fentanyl, which was launched in the fourth quarter of fiscal 2005. The Company considers a product to be a new product only in the year it is launched. Net revenues in fiscal 2006 however, did realize a significant benefit from a full year of sales of fentanyl, which accounted for over 10% of net revenues, as well as other products which were launched during fiscal 2005. The favorable impact of these products served to offset lower revenue on other products in the Company's portfolio, most notably omeprazole and carbidopa/levodopa. Both of these products realized lower net revenues as a result of increased competition. As is the case in the generic industry, the entrance into the market of other generic competition generally has a negative impact on the volume and pricing of the affected products.

As it relates to other products, the trend generally observed throughout the Company's product portfolio in fiscal 2006 was favorable volume which essentially offset unfavorable pricing. Doses shipped during fiscal 2006 were 12.6 billion, an increase over fiscal 2005 doses shipped of 12.5 billion.

The fiscal 2006 results include other revenue of \$17.2 million compared to \$5.6 million in the prior year. The majority of this increase relates to the sale of Apokyn in the current year, for which \$8.9 million of revenue was recognized. The remainder of the increase in fiscal 2006 is related to royalties.

Gross profit for fiscal 2006 was \$627.6 million, an increase of \$4.1 million or 1% over fiscal 2005, while gross margins were consistent at approximately 50%. A significant portion of gross profit was comprised of fentanyl. Absent any changes to market dynamics or the current competitive landscape for fentanyl, we expect the product to continue to be a significant contributor to sales and gross profit. Additionally, gross margins in the current year were impacted by favorable product mix, partially offset by lower margins on certain products, such as omeprazole and carbidopa/levodopa as a result of competition.

*Operating Expenses*

Research and development ( R&D ) expense for fiscal 2006 was \$102.1 million compared to \$87.9 million in fiscal 2005, which represents an increase of \$14.2 million or 16%. This increase is primarily due to costs incurred for clinical studies related to nebigolol incurred prior to the outlicensing of the product in the fourth quarter of fiscal 2006, as well as an overall increase in the number of ongoing studies. The Company's continued commitment to, and investment in, R&D activities have resulted in a robust ANDA pipeline, and it is expected that R&D expenses will continue to increase in future periods.

**Table of Contents**

SG&A expense for fiscal 2006 was \$225.8 million compared to \$259.5 million in fiscal 2005, a decrease of \$33.7 million or 13%. Included in fiscal 2005 SG&A were costs of \$22.9 million related to the terminated acquisition of King Pharmaceuticals, Inc. ( King ). Legal costs also decreased by approximately \$9.0 million from fiscal 2005 to fiscal 2006, primarily as a result of the timing of certain litigation. Legal challenges continue to be an integral part of the Company's strategy and its ability to continue to deliver new generic products to the market.

The remainder of the change in SG&A during fiscal 2006 is the result of the closure of Mylan Bertek as part of the Company's restructuring. Charges of \$19.9 million were incurred primarily in the first and second quarters related to employee termination and severance costs, lease termination costs and asset write-downs. These costs, which were primarily related to the termination of the Mylan Bertek sales force, resulted in significant cost savings realized throughout the remainder of fiscal 2006.

*Litigation Settlements, net*

Litigation settlements during fiscal 2006 consisted primarily of a charge of \$12.0 million for a contingent liability with respect to the Company's previously disclosed lorazepam and clorazepate product litigation. In the prior year, net gains of \$26.0 million were recorded with respect to settlement of other litigation.

*Interest Expense*

During the second quarter of fiscal 2006, Mylan completed a financing of \$500.0 million in Senior Notes and a \$500.0 million senior secured credit facility (see Contractual Obligations herein). Interest expense related to this financing was \$31.3 million for fiscal 2006. Included in interest expense is a commitment fee on the unused portion of the revolving credit facility and the amortization of financing fees.

*Other Income, net*

Other income, net of non-operating expenses, was \$18.5 million in fiscal 2006 compared to \$10.1 million in fiscal 2005. The increase is primarily the result of higher interest and dividend income on our investments in marketable securities as well as less of a loss recorded on our investment in Somerset.

We own a 50% equity interest in Somerset and account for this investment using the equity method of accounting. The recorded loss in Somerset for fiscal 2006 was \$2.5 million compared to a loss of \$3.3 million in fiscal 2005. As a result of the launch of EMSAM as previously discussed, we expect to realize income from Somerset in the foreseeable future.

*Income Taxes*

The effective income tax rate for fiscal 2006 was 32.8%, a decrease from the fiscal 2005 effective tax rate of 34.8%. During fiscal 2006, we recorded a tax benefit of \$7.5 million, primarily related to the resolution of certain tax positions with taxing authorities. These previously uncertain tax positions were resolved through the completion of audits or through the acceptance of our amended return filings. This tax benefit was partially offset by liabilities booked primarily for certain state tax filing positions. Despite our belief that our tax return positions are correct, we have established liabilities in both the current and prior fiscal years for these tax positions that may become payable in the event our positions are not upheld. In addition, the fiscal 2006 effective tax rate benefited from the new domestic production deduction and an increase in tax exempt interest as compared to the prior year, offset by higher state taxes.

**Fiscal 2005 Compared to Fiscal 2004***Total Revenues and Gross Profit*

Net revenues for fiscal 2005 were \$1.25 billion compared to \$1.36 billion for fiscal 2004, a decrease of \$107.4 million or 8%. 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

**Table of Contents**

our methodology with respect to such provisions. For the fiscal year ended March 31, 2005, the most significant amounts charged against gross revenues were for chargebacks in the amount of \$892.6 million and customer performance and promotions in the amount of \$195.1 million. For fiscal 2004, chargebacks of \$797.1 million and customer performance and promotions of \$163.8 million were charged against gross revenues. The increase in the amounts charged against gross revenues for chargebacks in the current year is primarily the result of pricing pressures on certain products in the Company's portfolio, most notably omeprazole, carbidopa/levodopa and Amnesteem<sup>®</sup>, as well as a shift in amounts purchased by customers that are entitled to chargeback credits. Customer performance and promotions include direct rebates as well as promotional programs. The increase in the amounts charged against gross revenues for customer performance and promotions is primarily due to increased gross revenues (from which direct rebates are calculated) and promotions offered to customers in connection with the launch of fentanyl.

The decrease in net revenues was primarily the result of continued pricing pressure, including the effect of additional competition, on the Company's product portfolio. Omeprazole, which was launched during the second quarter of fiscal 2004, experienced significantly lower pricing as a direct result of additional generic competition. Increased competition also resulted in unfavorable pricing on Amnesteem and carbidopa/levodopa, which also experienced a loss of market share. As is the case in the generic industry, the entrance into the market of other generic competition generally has a negative impact on the volume and pricing of the affected products. In the near term, it is likely that unfavorable pricing will continue to impact certain products in the Company's portfolio. Additionally, net revenues were impacted by certain customers that decreased their level of purchases in order to reduce the amount of Mylan's inventory that they maintain on their shelves.

Partially offsetting the impact of the items discussed above were increased overall volume and revenues from new products. Despite the additional competition experienced in the current year, omeprazole sales volume increased due primarily to expanding the customer base and capitalizing on a higher generic conversion rate. Also, Mylan was able to establish its position as market leader, based on omeprazole prescriptions dispensed. On an overall basis, volume shipped for the year increased over 5% to 12.5 billion doses compared with the prior year.

New products launched subsequent to March 31, 2004 contributed net revenues of \$87.3 million in the current fiscal year due largely to the launch of fentanyl in January 2005.

Fiscal 2004 other revenues included \$13.9 million from the sale of the U.S. and Canadian rights for sertaconazole nitrate 2% cream.

Consolidated gross profit for fiscal 2005 was \$623.5 million or 49.7% of revenues compared to \$762.5 million or 55.5% of revenues in fiscal 2004. The decrease in gross margin is primarily the result of price erosion brought about by additional generic competition on the Company's portfolio, primarily omeprazole and carbidopa/levodopa.

*Operating Expenses*

R&D expense for fiscal 2005 was \$87.9 million compared to \$100.8 million in fiscal 2004, which represents a decrease of \$12.9 million or 13%. This decrease is due primarily to the completion in late fiscal 2004 of clinical studies related to nebivolol, a product for the treatment of hypertension. The new drug application for nebivolol was submitted to the FDA on April 30, 2004 and accepted for filing by the FDA on June 29, 2004. Partially offsetting the decrease in R&D expenses as a result of nebivolol are increased R&D expenses related to other ongoing studies. The Company's continued commitment to, and investment in, R&D activities has resulted in a robust ANDA pipeline, with 44 applications pending before the FDA and 27 ANDA approvals in fiscal 2005, more than double the number from just two years ago. As clinical development programs for other products and life cycle management studies are initiated, it is expected that R&D expenses will increase in future periods.

SG&A expense for fiscal 2005 was \$259.5 million compared to \$201.6 million in fiscal 2004, an increase of \$57.9 million or 29%. Included in SG&A expense for fiscal 2005 are approximately \$18.3 million of costs

**Table of Contents**

directly related to the terminated King acquisition and an additional \$4.6 million of consulting expenses related to the planned integration of the two companies. The remainder of the increase in SG&A expense is due to numerous factors, the most significant of which is payroll and payroll-related costs, which increased by approximately \$9.8 million. Additionally, consulting expenses increased as a result of the Company's implementation of an enterprise resource planning ( ERP ) system, and legal expenses increased as a result of new and ongoing litigation related to patent challenges and other product-related matters. Legal challenges continue to be an integral part of the Company's strategy and its ability to continue to deliver new generic products to the market.

*Litigation Settlements, net*

Net gains of \$26.0 million were recorded in fiscal 2005 with respect to the settlement of various lawsuits. In June 2004, Mylan received \$37.5 million in settlement of certain patent litigation claims involving omeprazole. A portion of this settlement represented reimbursement of legal fees and expenses related to the litigation. Partially offsetting this gain, Mylan agreed, also in June 2004, to a \$9.0 million settlement resolving all pending litigation with respect to paclitaxel.

Net gains of \$34.8 million, also from the settlement of various lawsuits, were recorded in fiscal 2004. Of this, \$12.5 million was related to a favorable settlement reached with respect to the marketing and manufacturing of Zagam®, and \$10.2 million was related to a favorable settlement reached with respect to mirtazapine. The remainder of the settlement primarily relates to future payments to be made to Mylan totaling \$10.0 million from Mylan's co-defendants in the lorazepam and clorazepate litigation.

*Other Income, net*

Other income, net of other expenses, was \$10.1 million in fiscal 2005 compared to \$17.8 million in fiscal 2004. This decrease of \$7.7 million is primarily the result of lower realized gains on the sale of marketable securities in fiscal 2005 and a \$5.0 million gain on the sale of an office building recorded in fiscal 2004, partially offset by less of a loss recorded in fiscal 2005 on our investment in Somerset.

We own a 50% equity interest in Somerset and account for this investment using the equity method of accounting. The recorded loss in Somerset for fiscal 2005 was \$3.3 million compared to a loss of \$7.1 million in fiscal 2004. The investment in Somerset was reduced to zero during fiscal 2005. As such, in accordance with Accounting Principles Board ( APB ) Opinion No. 18, *The Equity Method of Accounting for Investments in Common Stock*, the Company temporarily ceased recording losses on this investment.

**Liquidity and Capital Resources**

The Company's primary source of liquidity continues to be cash flows from operating activities, which were \$416.6 million for fiscal 2006. Working capital as of March 31, 2006 was \$926.7 million, a decrease of \$356.3 million from the balance at March 31, 2005. The majority of this decrease was the result of net sales of marketable securities and lower accounts receivable, net. In addition to long-term borrowings, the Company used existing cash and marketable securities to finance certain transactions described below.

The decrease in accounts receivable, net, is due to the timing of cash collections since the end of fiscal 2005, primarily with respect to sales of fentanyl, which was launched in the fourth quarter.

During the third quarter of fiscal 2006, the Company received \$23.0 million related to the sale of the U.S. and Canadian rights for Apokyn. In fiscal 2006, \$8.9 million of revenue associated with the sale was recognized and included in other revenues. The remainder, net of certain related assets, has been recorded as deferred revenue. During the fourth quarter, Mylan received \$75.0 million related to its licensing agreement for nebivolol and has the potential to earn future milestone payments as well as royalties on nebivolol sales. Mylan also received payments totaling \$20.0 million with respect to other licensing agreements. These payments, along with the \$75.0 million, are also included in deferred revenue.

Cash provided by investing activities during fiscal 2006 was \$195.1 million. Of the Company's \$1.9 billion of total assets at March 31, 2006, \$518.1 million was held in cash, cash equivalents and marketable securities.

**Table of Contents**

Investments in marketable securities consist of a variety of high credit quality debt securities, including U.S. government, state and local government, and corporate obligations. These investments are highly liquid and available for working capital needs. As these instruments mature, the funds are generally reinvested in instruments with similar characteristics.

Capital expenditures during fiscal 2006 were \$103.7 million. These expenditures were incurred primarily with respect to the Company's planned expansions and the implementation of an ERP system. The Company anticipates that the majority of the remaining expenditures related to planned expansions and the ERP implementation will occur in fiscal 2007 and therefore expects capital expenditures for fiscal 2007 to be approximately \$100.0 million.

Cash used in financing activities was \$599.3 million for fiscal 2006. A total of \$1.26 billion was used during fiscal 2006 to repurchase Mylan common stock. Of this, \$1.0 billion was used to repurchase shares as part of the Company's modified Dutch Auction self-tender, with the remainder used to pay for expenses related to the self-tender and to repurchase shares under a previously announced open market follow-on repurchase program. In total, approximately 12.6 million shares were repurchased under the repurchase program in fiscal 2006 for approximately \$250.0 million.

Cash proceeds of \$775.0 million from the issuance of debt were received in the current year and used to partially finance the stock buybacks described above. During the fourth quarter of fiscal 2006, the Company made an optional principal payment of \$85.0 million on its term loan, in addition to the required 1% annual amortization. This amount was in excess of the mandatory repayment obligation. Financing fees of \$14.7 million were paid during fiscal 2006.

In order to provide additional operating leverage, if necessary, the Company maintains a revolving credit facility under its senior credit facility providing for borrowing of up to \$225.0 million. As of March 31, 2006, no funds were advanced under this facility.

Also included in cash flows from financing activities are proceeds of \$56.9 million from the exercise of stock options and cash dividends paid of \$49.8 million. In the first quarter of fiscal 2006, the Board of Directors voted to double the amount of the quarterly dividend to 6.0 cents per share from 3.0 cents per share, effective with the dividend paid for the first quarter of fiscal 2006.

Additionally, included in financing activities in fiscal 2006 was a \$21.8 million change in the amount of outstanding checks in excess of cash in our primary disbursement accounts. The Company utilizes a cash management system under which uncleared checks in excess of the cash balance in the bank account at the end of the reporting period are shown as a book cash overdraft. The Company transfers cash on an as-needed basis to fund clearing checks. The Company does not incur any financing charges with respect to this arrangement.

The Company is involved in various legal proceedings that are considered normal to its business (see Note 16 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 or to the Company upon the attainment of specified milestones. While these arrangements help to reduce the financial risk for unsuccessful projects, fulfillment of specified milestones resulting in either cash inflows or outflows 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.

**Table of Contents****Contractual Obligations**

The following table summarizes our contractual obligations at March 31, 2006 and the effect that such obligations are expected to have on our liquidity and cash flows in future periods:

| As of March 31, 2006        | Total        | Less<br>than<br>One<br>Year | One-Three<br>Years | Three-Five<br>Years | Thereafter |
|-----------------------------|--------------|-----------------------------|--------------------|---------------------|------------|
| <i>(in thousands)</i>       |              |                             |                    |                     |            |
| Operating leases            | \$ 9,911     | \$ 3,944                    | \$ 5,466           | \$ 321              | \$ 180     |
| Other long-term obligations | 22,435       | 1,821                       | 5,463              | 5,463               | 9,688      |
| Long-term debt              | 691,927      | 6,739                       | 8,250              | 176,938             | 500,000    |
| Scheduled interest payments | 286,889      | 42,660                      | 122,817            | 47,967              | 73,445     |
| Revolving credit facility   |              |                             |                    |                     |            |
| Letter of credit            | 975          | 975                         |                    |                     |            |
|                             | \$ 1,012,137 | \$ 56,139                   | \$ 141,996         | \$ 230,689          | \$ 583,313 |

We lease certain real property under various operating lease arrangements that expire generally over the next eight 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.

Long-term debt consists of \$500.0 million in Senior Notes and a \$275.0 million borrowing under a \$500.0 million senior secured credit facility. The Senior Notes consist of \$150.0 million of Senior Notes due 2010, and bearing interest at 5<sup>3</sup>/<sub>4</sub>% per annum (the 2010 Notes), and \$350.0 million of Senior Notes due 2015, and bearing interest at 6<sup>3</sup>/<sub>8</sub>% per annum (the 2015 Notes), and collectively, the Notes. The Senior Notes were originally issued on July 21, 2005, but were exchanged on January 14, 2006 in accordance with a registration rights agreement in a transaction consummated on January 19, 2006. The form and terms of the Senior Notes are identical in all material respects to the original notes except the transfer restrictions, registration rights and additional interest provisions relating to the original notes do not apply to the Notes. The senior secured credit facility, which was also entered into on July 21, 2005, consists of a \$225.0 million five-year revolving credit facility, which the Company expects to use for working capital and general corporate purposes, and a \$275.0 million five-year term loan, of which the balance is approximately \$188.0 million at March 31, 2006. The term loan bears interest at LIBOR plus 150 basis points or prime plus 50 basis points at the Company's option. The interest rate in effect on the term loan at March 31, 2006 was 6.33%. No borrowings were outstanding under the revolving credit facility at March 31, 2006.

Scheduled interest payments represent the estimated interest payments on the Notes and the senior secured credit facility. Variable debt interest payments are estimated using current interest rates, as discussed above.

Other long-term obligations, primarily deferred compensation, consist of the discounted future payments under individually negotiated agreements with certain key employees and directors.

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. In the event that all projects are successful, milestone and development payments of approximately \$13.7 million would be paid.

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





**Table of Contents**

The Company does not have material financial guarantees or other contractual commitments that are reasonably likely to adversely affect liquidity. The Company does not have any special purpose entities or off-balance sheet financing arrangements.

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.

**Application of Critical Accounting Policies**

Our significant accounting policies are described in Note 2 to 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 and the impact of existing legal matters.

*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 \$381.8 million and \$349.4 million at March 31, 2006 and 2005, respectively. Other current liabilities include \$60.4 million and \$51.8 million at March 31, 2006 and 2005, 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 fiscal year ended March 31, 2006:

|                                     | <b>Balance<br/>at<br/>March<br/>31,<br/>2005</b> | <b>Checks/Credits<br/>Issued to<br/>Third<br/>Parties</b> | <b>Current<br/>Provision<br/>Related to Sales<br/>Made in the<br/>Current Period</b> | <b>Balance<br/>at<br/>March<br/>31,<br/>2006</b> |
|-------------------------------------|--|---|--|--|
| (in thousands)                      |  |   |  |  |
| Chargebacks                         | \$ 166,066                                       | \$ (1,081,389)  | \$ 1,106,560   | \$ 191,237                                       |
| Customer performance and promotions | \$ 69,802  | \$ (167,837)  | \$ 160,797   | \$ 62,762  |
| Returns                             | \$ 46,544  | \$ (39,177)   | \$ 44,401  | \$ 51,768  |

The accrual for chargebacks increased primarily as a result of continued pricing pressures on certain products in the Company's portfolio, most notably omeprazole and carbidopa/levodopa, as well as an increase in amounts purchased by customers that are entitled to chargeback credits. No material amounts included in the provision for chargebacks recorded in the current period relate to sales made in the prior period.

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.

**Table of Contents**

*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 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 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.

*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



**Table of Contents**

Company's financial position or results of operations, such estimates are considered to be critical accounting estimates. During fiscal 2006, the Company recorded an accrual of \$12.0 million following a jury verdict of approximately that amount in the Company's lorazepam and clorazepate litigation. See ITEM 3, Legal Proceedings, for further discussion. After a review of all other legal proceedings in which we are involved, it was determined at March 31, 2006, that the conditions mentioned above were not met. The Company will continue to evaluate all legal matters as additional information becomes available.

**Recent Accounting Pronouncements**

In December 2004, the Financial Accounting Standards Board issued Statement of Financial Accounting Standards (SFAS) No. 123(R), *Share-Based Payment*. SFAS No. 123(R) establishes standards for the accounting for transactions in which an entity exchanges its equity instruments for goods and services. Under SFAS 123(R), companies will no longer be able to account for share-based compensation transactions using the intrinsic method in accordance with APB No. 25, *Accounting for Stock Issued to Employees*. Instead, companies will be required to account for such transactions using a fair-value method and to recognize compensation expense over the period during which an employee is required to provide services in exchange for the award. The Company has adopted SFAS No. 123(R) effective April 1, 2006. Based on the amount of options outstanding for which the requisite service has not yet been rendered by the employee, the Company expects to incur costs of approximately \$11.0 million, net of tax, in fiscal 2007 as a result of the adoption of this standard.

**ITEM 7A. Quantitative and Qualitative Disclosures about Market Risk**

The Company is subject to market risk from changes in the market values of investments in its marketable securities and interest rate risk from changes in interest rates associated with its long-term debt.

In addition to marketable debt and equity 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 following table summarizes the investments in marketable debt and equity securities which subject the Company to market risk at March 31, 2006 and 2005:

|                              | 2006       | 2005       |
|------------------------------|------------|------------|
| <i>(in thousands)</i>        |            |            |
| Marketable debt securities   | \$ 362,458 | \$ 667,170 |
| Marketable equity securities | 5,545      | 3,178      |
|                              | \$ 368,003 | \$ 670,348 |

**Marketable Debt Securities**

The primary objectives for the marketable 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. At March 31, 2006, the Company had invested \$362.5 million in marketable debt securities, of which \$82.4 million will mature within one year and \$280.1 million will mature after one year. The short duration to maturity creates minimal exposure to fluctuations in market values for investments that will mature within one year. However, a significant change in current interest rates could affect the market value of the remaining \$280.1 million of marketable debt securities that mature after one year. A 5% change in the market value of the marketable debt securities that mature after one year would result in a \$14.0 million change in marketable debt securities.

**Table of Contents**

*Long-Term Debt*

On July 21, 2005, the Company issued \$500.0 million in Senior Notes with fixed interest rates (which were exchanged for registered notes, as described previously) and entered into a \$500.0 million senior secured credit facility (the Credit Facility ). The Credit Facility consists of a \$225.0 million five-year revolving credit facility (the Revolving Credit Facility ) and a \$275.0 million five-year term loan (the Term Loan ). Loans under the Revolving Credit Facility bear interest at a rate equal to either LIBOR plus 1.25% or prime plus 0.25% per annum, at the Company's option, and the Term Loan bears interest at a rate equal to LIBOR plus 1.50% per annum or prime plus 0.50% per annum, also at the Company's option. At March 31, 2006, no amounts have been drawn under the revolving credit facility, and approximately \$188.0 million is outstanding under the Term Loan.

Generally, the fair market value of fixed interest rate debt will decrease as interest rates rise and increase as interest rates fall. As of March 31, 2006, the carrying value of our long-term debt approximated fair value. A 10% change in interest rates on the term loan would result in a change in interest expense of approximately \$1.2 million per year.

**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 March 31, 2006 and 2005</u>  | 40          |
| <u>Consolidated Statements of Earnings for the fiscal years ended March 31, 2006, 2005 and 2004</u>             | 41          |
| <u>Consolidated Statements of Shareholders' Equity for the fiscal years ended March 31, 2006, 2005 and 2004</u> | 42          |
| <u>Consolidated Statements of Cash Flows for the fiscal years ended March 31, 2006, 2005 and 2004</u>           | 43          |
| <u>Notes to Consolidated Financial Statements</u>   | 44          |
| <u>Management's Report on Internal Control over Financial Reporting</u>   | 63          |
| <u>Reports of Independent Registered Public Accounting Firm</u>   | 64          |
| <u>Supplementary Financial Information</u>  | 66          |



**Table of Contents**

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

| March 31,  | 2006         | 2005         |
|--|--------------|--------------|
| <b>Assets</b>  |              |              |
| Current assets:  |              |              |
| Cash and cash equivalents                                  | \$ 150,124   | \$ 137,733   |
| Marketable securities                                      | 368,003      | 670,348      |
| Accounts receivable, net                                   | 242,193      | 297,334      |
| Inventories  | 279,008      | 286,267      |
| Deferred income tax benefit                                | 137,672      | 119,327      |
| Prepaid expenses and other current assets                  | 14,900       | 17,443       |
| Total current assets                                       | 1,191,900    | 1,528,452    |
| Property, plant and equipment, net                         | 406,875      | 336,719      |
| Intangible assets, net                                     | 105,595      | 120,493      |
| Goodwill   | 102,579      | 102,579      |
| Other assets   | 63,577       | 47,430       |
| Total assets   | \$ 1,870,526 | \$ 2,135,673 |
| <b>Liabilities and shareholders equity</b>                 |              |              |
| Liabilities  |              |              |
| Current liabilities:                                       |              |              |
| Trade accounts payable                                     | \$ 76,859    | \$ 78,114    |
| Income taxes payable                                       | 12,963       | 44,123       |
| Current portion of long-term obligations                   | 4,336        | 1,586        |
| Cash dividends payable                                     | 12,605       | 8,078        |
| Other current liabilities                                  | 158,487      | 113,606      |
| Total current liabilities                                  | 265,250      | 245,507      |
| Deferred revenue   | 89,417       |              |
| Long-term debt   | 685,188      |              |
| Other long-term obligations                                | 22,435       | 19,325       |
| Deferred income tax liability                              | 20,585       | 24,905       |
| Total liabilities  | 1,082,875    | 289,737      |
| Shareholders equity  |              |              |
| Preferred stock par value \$0.50 per share                 |              |              |
| Shares authorized: 5,000,000 Shares issued: none           |              |              |
| Common stock par value \$0.50 per share                    |              |              |
| Shares authorized: 600,000,000 in 2006 and 2005            |              |              |
| Shares issued: 309,150,251 in 2006 and 304,434,724 in 2005 | 154,575      | 152,217      |
| Additional paid-in capital                                 | 418,954      | 354,172      |
| Retained earnings  | 1,939,045    | 1,808,802    |
| Accumulated other comprehensive earnings                   | 2,450        | 870          |

|   |              |              |
|---|--------------|--------------|
|   | 2,515,024    | 2,316,061    |
| Less treasury stock at cost                       |              |              |
| Shares: 98,971,431 in 2006 and 35,129,643 in 2005 | 1,727,373    | 470,125      |
| Total shareholders equity                         | 787,651      | 1,845,936    |
| Total liabilities and shareholders equity         | \$ 1,870,526 | \$ 2,135,673 |

*See Notes to Consolidated Financial Statements.*

**Table of Contents**

**Mylan Laboratories Inc.**  
**Consolidated Statements of Earnings**  
(in thousands, except per share data)

| Fiscal Year Ended March 31,                        | 2006              | 2005              | 2004              |
|--|-------------------|-------------------|-------------------|
| <b>Revenues:</b>                                   |                   |                   |                   |
| Net revenues                                       | \$ 1,239,988      | \$ 1,247,785      | \$ 1,355,150      |
| Other revenues                                     | 17,176            | 5,589             | 19,467            |
| <b>Total revenues</b>                              | <b>1,257,164</b>  | <b>1,253,374</b>  | <b>1,374,617</b>  |
| Cost of sales                                      | 629,548           | 629,834           | 612,149           |
| <b>Gross profit</b>                                | <b>627,616</b>    | <b>623,540</b>    | <b>762,468</b>    |
| <b>Operating expenses:</b>                         |                   |                   |                   |
| Research and development                           | 102,057           | 87,881            | 100,813           |
| Selling, general and administrative                | 225,754           | 259,478           | 201,612           |
| Litigation settlements, net                        | 12,417            | (25,990)          | (34,758)          |
| <b>Total operating expenses</b>                    | <b>340,228</b>    | <b>321,369</b>    | <b>267,667</b>    |
| <b>Earnings from operations</b>                    | <b>287,388</b>    | <b>302,171</b>    | <b>494,801</b>    |
| Interest expense                                   | 31,285            |                   |                   |
| Other income, net                                  | 18,502            | 10,076            | 17,807            |
| <b>Earnings before income taxes</b>                | <b>274,605</b>    | <b>312,247</b>    | <b>512,608</b>    |
| Provision for income taxes                         | 90,063            | 108,655           | 177,999           |
| <b>Net earnings</b>                                | <b>\$ 184,542</b> | <b>\$ 203,592</b> | <b>\$ 334,609</b> |
| <b>Earnings per common share:</b>                  |                   |                   |                   |
| Basic  | \$ 0.80           | \$ 0.76           | \$ 1.24           |
| Diluted  | \$ 0.79           | \$ 0.74           | \$ 1.21           |
| <b>Weighted average common shares outstanding:</b> |                   |                   |                   |
| Basic  | 229,389           | 268,985           | 268,931           |
| Diluted  | 234,209           | 273,621           | 276,318           |

*See Notes to Consolidated Financial Statements.*

**Table of Contents**

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

| Fiscal Year Ended March 31,   | 2006         | 2005         | 2004         |
|---|--------------|--------------|--------------|
| <b>Common stock shares issued:</b>  |              |              |              |
| Shares at beginning of year   | 304,434,724  | 303,553,121  | 300,904,262  |
| Stock options exercised   | 4,715,527    | 881,603      | 2,648,859    |
| Shares at end of year   | 309,150,251  | 304,434,724  | 303,553,121  |
| <b>Treasury stock:</b>  |              |              |              |
| Shares at beginning of year   | (35,129,643) | (35,129,643) | (29,143,443) |
| Issuance of restricted stock  | 35,463       |              | 472,500      |
| Stock purchases   | (63,877,251) |              | (6,458,700)  |
| Shares at end of year   | (98,971,431) | (35,129,643) | (35,129,643) |
| Common shares outstanding   | 210,178,820  | 269,305,081  | 268,423,478  |
| <b>Common stock, \$0.50 par:</b>  |              |              |              |
| Balance at beginning of year  | \$ 152,217   | \$ 151,777   | \$ 150,452   |
| Stock options exercised   | 2,358        | 440          | 1,325        |
| Balance at end of year  | 154,575      | 152,217      | 151,777      |
| <b>Additional paid-in capital:</b>  |              |              |              |
| Balance at beginning of year  | 354,172      | 338,143      | 304,350      |
| Stock options exercised   | 54,531       | 9,628        | 25,342       |
| Issuance of restricted stock  | 181          |              | 5,656        |
| Unearned compensation   | 3,142        | 3,901        | (9,352)      |
| Tax benefit of stock option plans   | 7,221        | 2,500        | 12,159       |
| Other   | (293)        |              | (12)         |
| Balance at end of year  | 418,954      | 354,172      | 338,143      |
| <b>Retained earnings:</b>   |              |              |              |
| Balance at beginning of year  | 1,808,802    | 1,637,497    | 1,330,933    |
| Net earnings  | 184,542      | 203,592      | 334,609      |
| Dividends declared (\$0.24 per share for fiscal 2006,<br>\$0.12 per share for fiscal 2005, \$0.10 per share for fiscal<br>2004) | (54,299)     | (32,287)     | (28,045)     |
| Balance at end of year  | 1,939,045    | 1,808,802    | 1,637,497    |
| <b>Accumulated other comprehensive earnings:</b>  |              |              |              |
| Balance at beginning of year  | 870          | 2,496        | 3,718        |
| Net unrealized gain (loss) on marketable securities   | 1,580        | (1,626)      | (1,222)      |

|  |             |              |              |
|--|-------------|--------------|--------------|
| Balance at end of year                                       | 2,450       | 870          | 2,496        |
| Treasury stock, at cost:                                     |             |              |              |
| Balance at beginning of year                                 | (470,125)   | (470,125)    | (343,121)    |
| Issuance of restricted stock                                 | 619         |              | 6,084        |
| Stock purchases  | (1,257,867) |              | (133,088)    |
| Balance at end of year                                       | (1,727,373) | (470,125)    | (470,125)    |
| Total shareholders equity                                    | \$ 787,651  | \$ 1,845,936 | \$ 1,659,788 |
| Comprehensive earnings:                                      |             |              |              |
| Net earnings   | \$ 184,542  | \$ 203,592   | \$ 334,609   |
| Other comprehensive earnings (loss), net of tax:             |             |              |              |
| Net unrealized holding gains (losses) gains on securities    | 1,397       | (1,711)      | 3,009        |
| Reclassification for losses (gains) included in net earnings | 183         | 85           | (4,231)      |
| Other comprehensive gain (loss), net of tax                  | 1,580       | (1,626)      | (1,222)      |
| Comprehensive earnings                                       | \$ 186,122  | \$ 201,966   | \$ 333,387   |

*See Notes to Consolidated Financial Statements.*

**Table of Contents**

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

| Fiscal Year Ended March 31,   | 2006        | 2005       | 2004       |
|---|-------------|------------|------------|
| <b>Cash flows from operating activities:</b>  |             |            |            |
| Net earnings  | \$ 184,542  | \$ 203,592 | \$ 334,609 |
| Adjustments to reconcile net earnings to net cash provided from operating activities: |             |            |            |
| Depreciation and amortization   | 46,827      | 45,100     | 44,323     |
| Realized gain on sale of marketable securities  |             |            | (6,509)    |
| Net loss from equity method investees   | 2,538       | 2,372      | 4,459      |
| Change in estimated sales allowances  | 41,047      | 108,778    | (24,016)   |
| Restructuring provision   | 20,921      |            |            |
| Deferred income tax (benefit) expense   | (23,635)    | (36,899)   | 32,275     |
| Gain on sale of building  |             |            | (5,000)    |
| Other non-cash items  | 15,768      | 7,951      | 765        |
| Loss (gain) from litigation, net  | 12,417      | (25,990)   | (34,758)   |
| Receipts from (payments of) litigation settlements, net                               | 1,691       | 42,990     | (16,630)   |
| Cash received from Somerset   |             |            | 10,000     |
| Changes in operating assets and liabilities:  |             |            |            |
| Accounts receivable   | 19,081      | (192,799)  | 18,617     |
| Inventories   | 6,012       | 34,530     | (83,020)   |
| Trade accounts payable  | 20,534      | 8,082      | (25,378)   |
| Income taxes  | (23,821)    | 22,010     | (11,096)   |
| Deferred revenue  | 106,642     |            |            |
| Other operating assets and liabilities, net   | (14,003)    | (16,006)   | (13,063)   |
| Net cash provided by operating activities   | 416,561     | 203,711    | 225,578    |
| <b>Cash flows from investing activities:</b>  |             |            |            |
| Proceeds from (purchase of):  |             |            |            |
| Capital assets  | (103,689)   | (90,746)   | (118,451)  |
| Reduction of investment in a limited liability partnership                            |             |            | 7,269      |
| Sale of assets  |             |            | 12,000     |
| Purchase of marketable securities   | (686,569)   | (780,806)  | (793,539)  |
| Proceeds from sale of marketable securities   | 991,060     | 693,289    | 640,511    |
| Other items, net  | (5,710)     | 3,372      | 1,884      |
| Net cash provided by (used in) investing activities                                   | 195,092     | (174,891)  | (250,326)  |
| <b>Cash flows from financing activities:</b>  |             |            |            |
| Cash dividends paid   | (49,772)    | (32,261)   | (26,024)   |
| Payment of financing fees   | (14,662)    |            |            |
| Proceeds from long-term debt  | 775,000     |            |            |
| Payment of long-term debt   | (87,062)    |            |            |
| Purchase of common stock  | (1,257,867) |            | (133,088)  |
| Proceeds from exercise of stock options   | 56,889      | 10,068     | 26,671     |

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|  |            |            |            |
|--|------------|------------|------------|
| (Decrease) increase in outstanding checks in excess of cash in disbursement accounts | (21,788)   | 19,622     | 9,771      |
| Net cash used in financing activities  | (599,262)  | (2,571)    | (122,670)  |
| Net increase (decrease) in cash and cash equivalents                                 | 12,391     | 26,249     | (147,418)  |
| Cash and cash equivalents beginning of year  | 137,733    | 111,484    | 258,902    |
| Cash and cash equivalents end of year  | \$ 150,124 | \$ 137,733 | \$ 111,484 |
| Supplemental disclosures of cash flow information:                                   |            |            |            |
| Cash paid during the year for:   |            |            |            |
| Income taxes   | \$ 137,519 | \$ 123,725 | \$ 156,821 |
| Interest   | \$ 29,110  | \$         | \$         |

*See Notes to Consolidated Financial Statements.*

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

Mylan Laboratories 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. The principal markets for these products are proprietary and ethical pharmaceutical wholesalers and distributors, drug store chains, drug manufacturers, institutions, and public and governmental agencies within the United States.

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

**Principles of Consolidation.** The Consolidated Financial Statements include the accounts of Mylan Laboratories Inc. and those of its wholly owned and majority-owned subsidiaries. All intercompany accounts and transactions have been eliminated in consolidation.

During the first quarter of fiscal 2006, Mylan announced that it was closing Mylan Bertek Pharmaceuticals Inc. (Mylan Bertek), its branded subsidiary. Mylan previously reported its financial results in two reportable segments, Generic and Brand. With the closure of Mylan Bertek, Mylan now reports one segment, and began reporting as such effective with the first quarter of fiscal 2006. 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 and reported as one segment.

**Cash Equivalents.** 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 \$7,605,000 and \$29,393,000 at March 31, 2006 and 2005, 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.

**Marketable Securities.** Marketable 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 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.

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 76% and 78% of the accounts receivable balances represent amounts due from three customers at March 31, 2006 and four customers at March 31, 2005, respectively. Total allowances for doubtful accounts were \$10,954,000 and \$7,340,000 at March 31, 2006 and 2005, respectively.

**Inventories.** Inventories are stated at the lower of cost or market, with cost determined by the first-in, first-out method.

We have made, are in the process of making and/or will scale-up and make commercial quantities of certain products prior to the date we anticipate that such products will receive final U.S. Food and Drug Administration (FDA) marketing approval and/or satisfactory resolution of patent infringement litigation involving them (i.e., pre-launch inventories). The scale-up and commercial production of pre-launch inventories involves the risk that such products may not be approved for marketing by the FDA on a timely basis, or ever, and/or that the outcome of related litigation may not be satisfactory. This risk notwithstanding,



**Table of Contents**

we plan to continue to scale-up and build pre-launch inventories of certain products that have not yet received final FDA approval and/or satisfactory resolution of patent infringement litigation when we believe that such action is appropriate in relation to the commercial value of the product launch opportunity.

As of March 31, 2006, we had approximately \$19,000,000 of inventory relating to products pending launch while we await receipt of final FDA marketing approval and/or satisfactory resolution of patent infringement litigation. The majority of our pre-launch inventories represent inventories for which we have received tentative approval from the FDA and are awaiting satisfactory resolution of patent infringement litigation.

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 10 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 \$32,126,000, \$26,455,000 and \$23,237,000 for fiscal years 2006, 2005 and 2004, respectively.

**Intangible Assets.** Intangible assets are stated at cost less accumulated amortization. Amortization is generally recorded on a straight-line basis over estimated useful lives ranging from 2 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.

**Impairment of Long-Lived Assets.** The carrying values of long-lived assets, which include property, plant and equipment and intangible assets with definite 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, and additional investments. Other assets are periodically reviewed for other-than-temporary declines in fair value.

**Revenue Recognition.** Mylan recognizes revenue for product sales upon shipment 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 fiscal year ended March 31, 2006. The following briefly describes the nature of each provision and how such provisions are estimated.

Discounts are reductions to invoiced amounts offered to customers for payment within a specified period and are estimated upon shipment 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

**Table of Contents**

provisions for rebates and other promotional programs based on the specific terms in each agreement at the time of shipment.

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 fiscal years ended March 31, 2006 and 2005. Such allowances were \$381,800,000 and \$349,355,000 at March 31, 2006 and 2005, respectively. Other current liabilities include \$60,374,000 and \$51,772,000 at March 31, 2006 and 2005, 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 Securities and Exchange Commission's (SEC) Staff Accounting Bulletin (SAB) No. 104, *Revenue Recognition, corrected copy* and Emerging Issues Task Force 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 on the consolidated statement of earnings. Additionally, included in other revenue for fiscal 2004, was \$13,910,000, representing income related to the sale of U.S. and Canadian rights for sertaconazole nitrate 2% cream.

The Company recognizes contract manufacturing and other service revenue when the service is performed or the product shipped, which is 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.

Three of the Company's customers accounted for 16%, 14% and 17% of the net revenues in fiscal 2006. Three customers accounted for 11%, 19% and 16%, respectively, of net revenues in fiscal 2005, and two customers accounted for 21% and 15%, respectively, of net revenues in fiscal 2004.

**Table of Contents**

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

| <b>Fiscal Year Ended March 31,</b> | <b>2006</b>  | <b>2005</b>  | <b>2004</b>  |
|------------------------------------|--------------|--------------|--------------|
| <i>(in thousands)</i>              |              |              |              |
| Central Nervous System             | \$ 475,898   | \$ 366,654   | \$ 322,790   |
| Cardiovascular                     | 422,727      | 484,588      | 530,613      |
| Dermatology                        | 72,843       | 74,048       | 102,513      |
| Gastrointestinal                   | 46,701       | 93,713       | 137,743      |
| Other <sup>(1)</sup>               | 221,819      | 228,782      | 261,491      |
|                                    | \$ 1,239,988 | \$ 1,247,785 | \$ 1,355,150 |

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

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

**Advertising Costs.** Advertising costs are expensed as incurred and amounted to \$5,435,000, \$9,745,000 and \$8,997,000 in fiscal years 2006, 2005 and 2004, respectively.

**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.

**Earnings per Common Share.** Basic earnings per common share is computed by dividing net earnings by the weighted average common shares outstanding for the period. Diluted earnings per common share is computed by dividing net earnings by the weighted average common shares outstanding adjusted for the dilutive effect of stock options, restricted stock or restricted units granted, excluding antidilutive shares, under our stock option plans (see Note 12). At March 31, 2006, 2005 and 2004, there were 312,750, 6,779,000 and 90,000 shares, respectively, that were antidilutive.

A reconciliation of basic and diluted earnings per common share is as follows:

| <b>Fiscal Year Ended March 31,</b>  | <b>2006</b> | <b>2005</b> | <b>2004</b> |
|---|-------------|-------------|-------------|
| <i>(in thousands, except per share data)</i>                                      |             |             |             |
| Net earnings  | \$ 184,542  | \$ 203,592  | \$ 334,609  |
| Weighted average common shares outstanding  | 229,389     | 268,985     | 268,931     |
| Assumed exercise of dilutive stock options, restricted stock and restricted units | 4,820       | 4,636       | 7,387       |
| Diluted weighted average common shares outstanding                                | 234,209     | 273,621     | 276,318     |
| Earnings per common share:  |             |             |             |
| Basic   | \$ 0.80     | \$ 0.76     | \$ 1.24     |
| Diluted   | \$ 0.79     | \$ 0.74     | \$ 1.21     |

**Stock Options.** In accordance with the provisions of SFAS No. 123, *Accounting for Stock-Based Compensation*, and SFAS No. 148, *Accounting for Stock-Based Compensation-Transition and Disclosure, an amendment of FASB Statement No. 123*, the Company accounts for its stock option plans under the intrinsic-value-based method as defined in Accounting Principles Board ( APB ) Opinion No. 25, *Accounting for Stock Issued to Employees*. The following table illustrates the effect on net earnings and earnings per share if

47

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**Table of Contents**

the Company had applied the fair value recognition provisions of SFAS No. 123 to stock-based employee compensation:

| Fiscal Year Ended March 31,  | 2006       | 2005       | 2004       |
|--|------------|------------|------------|
| <i>(in thousands, except per share data)</i>   |            |            |            |
| Net earnings, as reported  | \$ 184,542 | \$ 203,592 | \$ 334,609 |
| Add: Stock-based compensation expense included in reported net earnings, net of related tax effects                          | 2,649      | 2,543      | 1,553      |
| Deduct: Total compensation expense determined under fair-value based method for all stock awards, net of related tax effects | (11,845)   | (14,852)   | (24,674)   |
| Pro forma net earnings   | \$ 175,346 | \$ 191,283 | \$ 311,488 |
| Earnings per share:  |            |            |            |
| Basic as reported  | \$ 0.80    | \$ 0.76    | \$ 1.24    |
| Basic pro forma  | \$ 0.76    | \$ 0.71    | \$ 1.16    |
| Diluted as reported  | \$ 0.79    | \$ 0.74    | \$ 1.21    |
| Diluted pro forma  | \$ 0.75    | \$ 0.70    | \$ 1.14    |

**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.

**Reclassification.** Certain prior year amounts were reclassified to conform to the fiscal 2006 presentation.

**Fiscal Year.** The Company's fiscal year ends on March 31. All references to fiscal year shall mean the 12 months ended March 31.

**Recent Accounting Pronouncements.** In December 2004, the Financial Accounting Standards Board ( FASB ) issued SFAS No. 123(R), *Share-Based Payment*. SFAS No. 123(R) establishes standards for the accounting for transactions in which an entity exchanges its equity instruments for goods and services. Under SFAS No. 123(R), companies will no longer be able to account for share-based compensation transactions using the intrinsic method in accordance with APB No. 25. Instead, companies will be required to account for such transactions using a fair-value method and to recognize compensation expense over the period during which an employee is required to provide services in exchange for the award. The Company has adopted SFAS No. 123(R) effective April 1, 2006. Based on the amount of options outstanding for which the requisite service has not yet been rendered by the employee, the Company expects to incur costs of approximately \$11,000,000, net of tax, in fiscal 2007 as a result of the adoption of this standard.

**Note 3. 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 \$20,921,000, pre-tax, during the year ended March 31, 2006. Of this, \$1,000,000 is included in research and development expense, with the remainder in selling, general and administrative expense. As of March 31, 2006, the Company's



**Table of Contents**

restructuring was substantially complete. The major components of the restructuring charge and the remaining accrual balance at March 31, 2006, were as follows:

|                             |                | Non-Cash<br>Asset<br>Write-downs | Employee<br>Termination and<br>Severance Costs | Other<br>Exit Costs | Total    |
|-----------------------------|----------------|----------------------------------|--|---------------------|----------|
| <i>(in thousands)</i>       |                |                                  |  |                     |          |
| Accrued restructuring costs | March 31, 2005 | \$                               | \$   | \$                  | \$       |
| Restructuring charge        | fiscal 2006    | 1,636                            | 15,117   | 4,168               | 20,921   |
| Amounts utilized            | fiscal 2006    | (1,636)                          | (14,603)                                       | (2,516)             | (18,755) |
| Accrued restructuring costs | March 31, 2006 | \$                               | \$   | 514                 | \$ 2,166 |

Employee termination and severance costs were primarily related to involuntary terminations, most of which were with respect to the Mylan Bertek sales force, and represent cash termination payments paid to the affected employees as a direct result of the restructuring. Exit costs consist primarily of lease termination costs incurred as a result of the restructuring.

**Note 4. Balance Sheet Components**

Selected balance sheet components consist of the following at March 31:

|  | 2006       | 2005       |
|--|------------|------------|
| <i>(in thousands)</i>                      |            |            |
| Inventories:                               |            |            |
| Raw materials                              | \$ 98,259  | \$ 119,654 |
| Work in process                            | 36,073     | 39,589     |
| Finished goods                             | 144,676    | 127,024    |
|  | \$ 279,008 | \$ 286,267 |
| Property, plant and equipment:             |            |            |
| Land and improvements                      | \$ 10,639  | \$ 9,704   |
| Buildings and improvements                 | 175,343    | 161,050    |
| Machinery and equipment                    | 287,202    | 269,208    |
| Construction in progress                   | 144,429    | 85,324     |
|  | 617,613    | 525,286    |
| Less accumulated depreciation              | 210,738    | 188,567    |
|  | \$ 406,875 | \$ 336,719 |
| Other current liabilities:                 |            |            |
| Payroll and employee benefit plan accruals | \$ 24,323  | \$ 21,251  |
| Accrued rebates                            | 60,374     | 51,772     |
| Royalties and product license fees         | 9,320      | 11,446     |
| Deferred revenue                           | 17,225     |            |
| Legal and professional                     | 30,074     | 18,148     |
| Other                                      | 17,171     | 10,989     |

\$ 158,487 \$ 113,606



**Table of Contents**

**Note 5. Marketable Securities**

The amortized cost and estimated fair value of marketable securities are as follows:

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