

MYLAN LABORATORIES INC

Form 10-K

May 20, 2005

**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, 2005**

**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:**

**Title of Each Class:**  
Common Stock, par value \$0.50 per share

**Name of Each Exchange on Which Registered:**  
New York Stock Exchange

**Securities registered pursuant to Section 12(g) of the Act:** None

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 an accelerated filer (as defined in Rule 12b-2 of the Exchange 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, 2004, the last business day of the registrant's most recently completed second fiscal quarter, was approximately \$4,705,144,650.

The number of outstanding shares of common stock of the registrant as of May 11, 2005, was 269,342,141.

---

**MYLAN LABORATORIES INC.**

**INDEX TO FORM 10-K  
For the Fiscal Year Ended March 31, 2005**

|   | <b>Page</b> |
|---|-------------|
| <b><u>PART I</u></b>  |             |
| <u>ITEM 1. Business</u>   | 3           |
| <u>Overview of Our Business</u>   | 3           |
| <u>Generic Segment</u>  | 3           |
| <u>Brand Segment</u>  | 4           |
| <u>Product Development</u>  | 5           |
| <u>Generic Product Development</u>  | 5           |
| <u>Brand Product Development</u>  | 6           |
| <u>Terminated Acquisition of King Pharmaceuticals</u>   | 7           |
| <u>Patents, Trademarks and Licenses</u>   | 8           |
| <u>Customers and Marketing</u>  | 8           |
| <u>Competition</u>  | 8           |
| <u>Product Liability</u>  | 8           |
| <u>Raw Materials</u>  | 9           |
| <u>Government Regulation</u>  | 9           |
| <u>Seasonality</u>  | 10          |
| <u>Environment</u>  | 10          |
| <u>Employees</u>  | 10          |
| <u>Backlog</u>  | 10          |
| <u>Risk Factors</u>   | 10          |
| <u>Securities Exchange Act Reports</u>  | 19          |
| <u>ITEM 2. Properties</u>   | 19          |
| <u>ITEM 3. Legal Proceedings</u>  | 20          |
| <u>ITEM 4. Submission of Matters to a Vote of Security Holders</u>  | 22          |
| <b><u>PART II</u></b>   |             |
| <u>ITEM 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u> | 23          |
| <u>ITEM 6. Selected Financial Data</u>  | 24          |
| <u>ITEM 7. Management's Discussion and Analysis of Results of Operations and Financial Condition</u>                        | 25          |
| <u>ITEM 7A. Quantitative and Qualitative Disclosures about Market Risk</u>  | 37          |
| <u>ITEM 8. Financial Statements and Supplementary Data</u>  | 38          |
| <u>ITEM 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</u>                         | 63          |
| <u>ITEM 9A. Controls and Procedures</u>   | 63          |

PART III

|  |    |
|--|----|
| <u>ITEM 10. Directors and Executive Officers of the Registrant</u>   | 64 |
| <u>ITEM 11. Executive Compensation</u>   | 64 |
| <u>ITEM 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u> | 64 |
| <u>ITEM 13. Certain Relationships and Related Transactions</u>   | 64 |
| <u>ITEM 14. Principal Accounting Fees and Services</u>   | 64 |

PART IV

|  |    |
|--|----|
| <u>ITEM 15. Exhibits and Financial Statement Schedules</u> | 64 |
| <u>Signatures</u>  | 69 |
| <u>Exhibit 10.4(B)</u>                                     |    |
| <u>Exhibit 10.4(C)</u>                                     |    |
| <u>Exhibit 21</u>  |    |
| <u>Exhibit 23</u>  |    |
| <u>Exhibit 31.1</u>  |    |
| <u>Exhibit 31.2</u>  |    |
| <u>Exhibit 32</u>  |    |

**Table of Contents**

**PART I**

**ITEM 1. Business**

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

**Overview of Our Business**

We conduct business through our generic ( Generic Segment ) and brand ( Brand Segment ) pharmaceutical operating segments. For fiscal 2005, the Generic Segment represented approximately 81% of net revenues, and the Brand Segment represented approximately 19% of net revenues. For both fiscal 2004 and 2003, the Generic Segment represented approximately 80% of net revenues, and the Brand Segment represented approximately 20% of net revenues. The financial information for our operating segments required by this Item is provided in Note 13 to the Consolidated Financial Statements under Part II, Item 8, of this Annual Report on Form 10-K.

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. 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.

**Generic Segment**

We are recognized as a leader in the generic pharmaceutical industry. The Generic Segment consists of two principal business units, Mylan Pharmaceuticals Inc. ( MPI ) and UDL Laboratories, Inc. ( UDL ), both of which are wholly owned subsidiaries of Mylan. MPI is our primary generic pharmaceutical research, development, manufacturing, marketing and distribution subsidiary. MPI's net revenues are derived primarily from the sale of solid oral dosage products. UDL packages and markets generic products, either obtained from MPI or purchased from third parties, in unit dose formats, for use primarily in hospitals and other institutions. The Generic Segment is augmented by transdermal patch products which are developed and manufactured by Mylan Technologies Inc. ( Mylan Tech ), a wholly owned subsidiary of Mylan. As discussed below, Mylan Tech is a component of our Brand Segment.

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 is first to file 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 certification, commonly referred to as a Paragraph IV certification, results in a period of generic marketing exclusivity. This exclusivity, which under certain circumstances may be required to be shared with other applicable ANDA sponsors with Paragraph IV certifications, lasts for 180 days during which the FDA cannot grant final approval to other ANDA sponsors holding applications for the same generic equivalent.

## **Table of Contents**

An ever-increasing trend in the pharmaceutical industry involves the practice of so-called 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 period, and, exclusivity aside, could significantly lower the price at which the generic company could otherwise sell their product upon launch. During fiscal 2005, Mylan launched two products, nitrofurantoin monohydrate/macrocrystals capsules, the generic equivalent of Procter & Gamble's Macrobid®, and a fentanyl transdermal system, the generic equivalent of Alza Corporation's Duragesic®, both of which were significantly negatively impacted by authorized generics. See Risk Factors beginning on page 10 for further discussion of risks associated with our industry.

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.

Mylan manufactures approximately 95% of all doses sold by our Generic Segment. Our product portfolio consists of over 140 generic pharmaceutical products, including approximately 135 in capsule or tablet form in an aggregate of approximately 360 dosage strengths, with 10 extended release products in 19 dosage strengths of which three are transdermal patches in 12 dosage strengths. In addition to those products manufactured by Mylan, we are marketing 63 generic products in 108 dosage strengths under supply and distribution agreements with other pharmaceutical companies. As of December 31, 2004, 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 70% of the generic pharmaceutical products we marketed, excluding unit-dose products.

Approximately 17% of the Generic Segment's net revenues in fiscal years 2005 and 2004 and 20% of the Generic Segment's net revenues in fiscal 2003 were contributed by calcium channel blockers, primarily nifedipine.

The future success of our Generic Segment is partially dependent upon continued increasing market acceptance of generic products as substitutes for existing products. Additionally, we expect that future growth of our Generic Segment 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. In addition, we intend to continue to seek complementary strategic acquisitions of both companies and products.

## **Brand Segment**

The Brand Segment consists of two principal business units, Mylan Bertek Pharmaceuticals Inc. ( Mylan Bertek ) and Mylan Tech, both of which are wholly owned subsidiaries of Mylan. Mylan Bertek's principal therapeutic areas of concentration include neurology, dermatology and cardiology. The Brand Segment includes pharmaceutical products that have patent protection, have achieved brand recognition in the marketplace or represent branded generic pharmaceutical products that are responsive to promotional efforts.

We expect that the growth of the Brand Segment will be driven through internal development of unique and innovative products, product or business acquisitions and licensing arrangements. Additionally, the growth of the

Brand Segment will be impacted by our ability, through continued marketing efforts, to increase prescriptions for our current products.

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 accepted for filing during the second quarter of fiscal 2005. As a result of recent actions taken by the U.S. Patent and Trademark Office, the nebivolol compound now has patent protection in the U.S. into 2020, which may be extended under the terms of the Waxman-Hatch Act.

During fiscal 2005, Mylan Bertek received FDA approval for Apokyn™ (apomorphine hydrochloride injection), as the first and only therapy in the U.S. for the acute, intermittent treatment of hypomobility, off episodes associated with



## **Table of Contents**

advanced Parkinson's disease. Apokyn, which has orphan drug status, was launched during the second quarter of fiscal 2005.

The Brand Segment sales force consists of approximately 190 sales representatives and managers who promote our products to primary care physicians, dermatologists, neurologists, pharmacists, managed care organizations, governmental agencies, independent pharmacies and chain drug stores.

## **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 \$87.9 million, \$100.8 million and \$86.7 million in fiscal 2005, 2004 and 2003, respectively. Our research and development strategy focuses on 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 products with respect to additional dosage strengths;

- completion of additional preclinical and clinical studies for approved NDA products required by the FDA, known as 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 our 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.

*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 ANDAs and NDAs 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 approval process is generally less time-consuming and complex than the NDA approval process. It 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 does, however, require one or more bioequivalency studies to

## **Table of Contents**

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, bioequivalency 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 bioequivalency studies are conducted or other requirements are satisfied.

During fiscal 2005, Mylan received 27 application approvals from the FDA, including 11 final ANDA approvals, 11 tentative ANDA approvals and five supplemental ANDA approvals for new product strengths. Over the past two fiscal years, the number of ANDA approvals has more than doubled. This 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, 2005, Mylan had 42 original ANDAs and two supplemental ANDAs for new product strengths pending FDA approval, which represent products with calendar year 2004 brand sales of approximately \$35 billion. Of these 44 applications, 18 have been granted tentative approval/approvable status and represent approximately \$19 billion in calendar year 2004 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.

Over the next few years, patent protection on a large number of brand drugs is expected to expire. 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, 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. During fiscal 2006, we plan to invest in a significant number of bioequivalency studies for development of generic products or dosage forms.

## **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 application ( IND ), which must become effective before clinical studies may begin;

adequate and well-controlled human clinical studies to establish the safety and efficacy of the proposed product for its intended use;

submission of an NDA containing the results of the preclinical tests and clinical studies establishing the safety and efficacy of the proposed product for its intended use, as well as extensive data addressing such matters 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 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-

## **Table of Contents**

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

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

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

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

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

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

Our brand product development continues to emphasize areas where we have an existing sales and marketing presence, namely dermatology, cardiology and neurology.

Additionally, pending ANDA submissions or products in development that upon FDA approval may require significant promotional efforts, may be marketed by the Brand Segment.

The Company owns a 50% interest in Somerset Pharmaceuticals, Inc. ( Somerset ), a joint venture with Watson Pharmaceuticals, Inc. Currently, Somerset s only marketed product is Eldepryl®, a drug for the treatment of patients with late stage Parkinson s disease. In recent years, Somerset has increased its research and development spending to develop additional indications for selegiline, the active ingredient of Eldepryl, using a transdermal delivery system. In May 2001, Somerset filed an NDA for EMSAM™ (selegiline transdermal delivery system), a transdermal therapy for which it is seeking an indication for the treatment of major depressive disorder. In December 2004, Somerset entered into an agreement with Bristol-Myers Squibb for the commercialization and distribution of Somerset s EMSAM. During fiscal 2004, Somerset received an Approvable letter from the FDA with regard to the EMSAM NDA. As Somerset continues its research and development activities, including working with the FDA to obtain approval for EMSAM, its earnings may continue to be adversely affected.

## **Terminated Acquisition of King Pharmaceuticals**

On July 23, 2004, we entered into an Agreement and Plan of Merger ( Agreement ) to acquire King Pharmaceuticals, Inc. ( King ) in a stock-for-stock transaction. On February 27, 2005, Mylan and King announced that the companies had mutually agreed to terminate the Agreement. Following the termination of the Agreement, in the fourth quarter of fiscal 2005, Mylan recorded expenses of approximately \$18.3 million for costs directly related to the terminated acquisition. An additional \$4.6 million of expenses were incurred during fiscal 2005 consisting of consulting costs related to the planned integration of the two companies.

## **Table of Contents**

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

We own or license a number of patents in the U.S. and foreign countries covering certain products, and have also developed brand names and trademarks for other products. Generally, the brand pharmaceutical business relies upon patent protection to ensure market exclusivity for the life of the patent. 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 in the Brand Segment 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 and group purchasing organizations within the U.S. We also market our generic products indirectly to independent pharmacies, managed care organizations, hospitals, nursing homes, pharmacy benefit management companies and government entities. These customers, called indirect customers, purchase our products primarily through our wholesale customers. Approximately 68 employees are engaged in servicing Generic Segment customers.

Brand pharmaceutical products are marketed directly to health care professionals in order to increase brand awareness and prescriptions written for the product. However, these products are generally sold through the same channels and customers as generic products. Approximately 265 employees are engaged in marketing and selling the Brand Segment's products, as well as servicing Brand Segment 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. In addition to returns, 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 additional revenue provisions.

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. Sales of products to AmerisourceBergen Corporation, Cardinal Health, Inc. and McKesson Corporation represented approximately 20%, 16% and 14%, respectively, of net revenues in fiscal 2003.

### **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 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 and by developing therapeutic equivalents to brand products that offer unique marketing opportunities.

### **Product Liability**

Product liability litigation represents an inherent risk to firms in the pharmaceutical industry. We maintain commercial insurance to protect against and manage a portion of the risks involved in conducting our business. The cost to obtain insurance coverage for pharmaceutical product liability risks has significantly increased due to the commercial insurance

## **Table of Contents**

industry's practices resulting in increased retentions and changes in the limits of insurance coverage. In response to the rising cost of commercial insurance, Mylan reinstated the use of our wholly owned captive insurance subsidiary to insure a portion of these risks including the first \$10.0 million. Mylan purchases commercial insurance in excess of this \$10.0 million limit.

## **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 only available from a single FDA-approved supplier. Even when more than one supplier exists, we may choose, and in some cases have only chosen to list, one supplier in our applications submitted to the FDA. Any change in a supplier not previously approved must then be submitted through a formal approval process with the FDA.

## **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, record keeping, 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 that the listed patent is either 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

## **Table of Contents**

between the average net sales price and the lowest net sales 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.

## **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 3,000 persons, approximately 1,080 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 Paper, Allied-Industrial Chemical and Energy Workers International Union (P.A.C.E.) (AFL-CIO) and its Local Union 5-957-AFL-CIO under a contract that expires on April 15, 2007.

## **Backlog**

At May 11, 2005, Generic Segment open orders were approximately \$22.0 million and Brand Segment open orders were approximately \$6.0 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.

## **Risk Factors**

The following risk factors could have a material adverse effect on our business, financial position or results of operations and could cause the market value of our common stock to decline. These risk factors may not include all of the important factors that could affect our business or our industry or that could cause our future financial results to differ materially from historic or expected results or cause the market price of our common stock to fluctuate or decline.

**OUR FUTURE REVENUE GROWTH AND PROFITABILITY ARE DEPENDENT UPON OUR ABILITY TO DEVELOP AND 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 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 may not be successful in commercializing any of the products that we are developing or licensing 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 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

## Table of Contents

may obtain raw materials or produce batches of inventory to be used in efficacy and bioequivalency 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, 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.

### **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. In some cases, these 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 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.**

**Table of Contents**

Sales of a limited number of our products often represent a significant portion of our net revenues 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;

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.

**Table of Contents**

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.

**OUR REPORTING AND PAYMENT OBLIGATIONS UNDER THE MEDICAID REBATE PROGRAM AND OTHER GOVERNMENTAL PRICING 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.**

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. Although the regulations regarding reporting and payment obligations are complex, we believe we are properly and accurately calculating and reporting the amounts owed in respect of Medicaid and other governmental pricing programs; however, our calculations are subject to review and challenge by the applicable governmental agencies, and it is possible that any such review 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, these calculations are subject to the risk of errors. 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, our 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, 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.**

**Table of Contents**

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 SO-CALLED 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 a so-called 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.

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.

**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**

**Table of Contents**

**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.

**WE USE SEVERAL MANUFACTURING FACILITIES TO MANUFACTURE OUR PRODUCTS. HOWEVER, A SIGNIFICANT NUMBER OF OUR GENERIC 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 generic 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.

**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 our patents are found to be non-infringed, invalid or not enforceable, we could experience an adverse effect on our ability to commercially promote 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 OR OTHER THIRD PARTIES MAY ALLEGE THAT WE ARE INFRINGING THEIR INTELLECTUAL PROPERTY, FORCING US TO EXPEND SUBSTANTIAL RESOURCES IN RESULTING**

**Table of Contents**

**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) by our competitors 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 unclear, 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 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,

**Table of Contents**

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.

**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 GENERICS 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.**

If recent FDA rulings should stand, which rulings we believe 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, then our business and the generic industry as a whole could be materially adversely affected. While we remain in an intense battle with regard to these recent decisions as well as current brand tactics that undermine Congressional intent, we cannot guarantee that we will prevail. If we are not successful, 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 Securities and Exchange Commission ( 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 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.

**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, JUDGEMENTS 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,

**Table of Contents**

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.

**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 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 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>Primary Segment</b> | <b>Location</b> | <b>Status</b>                                  | <b>Primary Use</b>   |
|------------------------|-----------------|--|--|
| Generic:               | North Carolina  | Owned  | Distribution<br>Warehousing  |
|                        |                 | Owned  | Manufacturing<br>Warehousing<br>Research and Development<br>Administrative |
|                        | West Virginia   | Leased   | Warehousing<br>Administrative  |
|                        |                 | Owned  | Manufacturing<br>Warehousing<br>Administrative                             |
|                        | Illinois        | Owned  | Manufacturing<br>Warehousing<br>Administrative                             |
|                        |                 | Leased   | Warehousing  |
| Puerto Rico            | Owned           | Manufacturing<br>Warehousing<br>Administrative |  |
|                        | Leased          | Administrative                                 |  |
| Brand:                 | North Carolina  | Leased   | Administrative   |

Edgar Filing: MYLAN LABORATORIES INC - Form 10-K

|                  |              |       |  |
|------------------|--------------|-------|--|
|                  | Texas        | Owned | Manufacturing<br>Warehousing   |
|                  | Vermont      | Owned | Manufacturing<br>Research and Development<br>Administrative<br>Warehousing |
| Corporate/Other: | Pennsylvania | Owned | Administrative   |

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.

**Table of Contents**

**ITEM 3. Legal Proceedings**

**Legal Proceedings**

While it is not possible to determine with any degree of certainty the ultimate outcome of the following legal proceedings, the Company believes that it has meritorious defenses with respect to the claims asserted against it and intends to vigorously defend its position. An adverse outcome in any of these proceedings could have a material adverse effect on the Company's financial position and results of operations.

*Omeprazole*

In fiscal 2001, Mylan Pharmaceuticals Inc. ( MPI ), a wholly-owned subsidiary of Mylan Laboratories Inc. ( Mylan Labs ), filed an Abbreviated New Drug Application ( ANDA ) seeking approval from the Food and Drug Administration ( FDA ) to manufacture, market and sell omeprazole delayed-release capsules, and made Paragraph IV certifications to several patents owned by AstraZeneca PLC ( AstraZeneca ) that were listed in the FDA's Orange Book . On September 8, 2000, AstraZeneca filed suit against MPI and Mylan Labs in the U.S. District Court for the Southern District of New York alleging infringement of several of AstraZeneca's patents. MPI filed multiple motions for summary judgment as to all claims of infringement, and the summary judgment motions remain pending. 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.

In November 2002, MPI filed suit in the U.S. District Court for the District of Delaware against Kremers Urban Development Company ( KUDCo ) and several other companies affiliated with Schwarz Pharma AG (the Schwarz Pharma Group ) alleging KUDCo and the Schwarz Pharma Group are infringing U.S. patent 5,626,875 (the 875 Patent ) in connection with KUDCo's manufacture and sale of omeprazole capsules in the U.S. KUDCo and the Schwarz Pharma Group asserted defenses and counterclaims in that action alleging the inventors listed on the 875 Patent are not the actual inventors of the invention described therein, and further seeking money damages alleging the infringement action was not proper. On August 7, 2003, KUDCo and an individual filed a lawsuit against MPI and Esteve in the U.S. District Court for the District of Columbia asserting claims that were not asserted in the Delaware action. During the first quarter of fiscal 2005, a settlement was agreed to with respect to the cases involving MPI, KUDCo and the Schwarz Pharma Group, and these lawsuits have been dismissed, with prejudice. Under the settlement, MPI received a payment of \$37.5 million, a portion of which represented the reimbursement of legal expenses.

*Lorazepam and Clorazepate*

The Company previously reported final court approval in the first quarter of fiscal 2004 of a settlement of a direct purchaser class action related to the sale of lorazepam and clorazepate, which settlement did not include several related cases. Trial on the last remaining case began on May 3, 2005, involving an action brought by a group of health insurers who opted out of previous class action settlements. These plaintiffs are seeking to recover approximately \$12.0 million in damages, plus possible trebling and attorneys' fees.

*Pricing and Medicaid Litigation*

On September 26, 2003, the Commonwealth of Massachusetts sued Mylan Labs and 12 other generic drug companies alleging unlawful manipulation of reimbursements under the Massachusetts Medicaid program. The lawsuit identified three drug products sold by MPI, and sought equitable relief, attorneys' fees, cost of litigation and monetary damages in unspecified sums. The court has dismissed the complaint, without prejudice, and granted Massachusetts leave to amend.

On June 26, 2003, UDL Laboratories, Inc. ( UDL ) and MPI received requests from the U.S. House of Representatives Energy and Commerce Committee requesting information about certain drug products sold by UDL and MPI, in connection with the Committee's investigation into pharmaceutical reimbursement and rebates under Medicaid. UDL and MPI are cooperating with this inquiry and provided information in response to the Committee's requests in 2003. Several states' Attorneys General ( AGs ) have also sent letters to MPI, UDL and Mylan Bertek Pharmaceuticals Inc. ( Mylan Bertek ), a wholly-owned subsidiary of Mylan Labs, demanding that those companies retain documents relating to Medicaid

**Table of Contents**

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. Mylan is cooperating with each of these investigations and has begun producing information in response to the subpoenas.

On August 4, 2004, the City of New York filed a civil lawsuit against 44 pharmaceutical companies, including Mylan Labs, in the U.S. District Court for the Southern District of New York alleging violations of federal and state Medicaid laws, Medicaid and common law fraud, breach of contract, other New York statutes and regulations, and unjust enrichment, and on January 26, 2005, the plaintiff filed an amended complaint naming MPI and UDL as defendants. The case has been transferred to the AWP multi-district litigation proceedings pending in the U.S. District Court for the District of Massachusetts for pretrial proceedings. A similar suit was filed by the Commonwealth of Kentucky on November 4, 2004, against Mylan Labs, MPI and approximately 40 other pharmaceutical companies in the Franklin County Circuit Court alleging violations of the Kentucky Consumer Protection Act, the Kentucky Medicaid Fraud Statute, the Kentucky False Advertising Statute, fraud and negligent misrepresentation relating to reporting of average wholesale prices (AWP). In addition, on December 6, 2004, the State of Wisconsin sued Mylan Labs, MPI and approximately 35 other pharmaceutical companies in the Circuit Court for Dane County, Wisconsin alleging violations of Wisconsin false advertising, price reporting and fraud statutes and, the Wisconsin Trusts and Monopolies Act, and also asserting a claim for unjust enrichment. Nassau County, New York filed a similar complaint in the U.S. District Court for the Eastern District of New York on November 24, 2004 containing federal and state claims against numerous pharmaceutical companies including Mylan Labs, MPI and UDL. On January 26, 2005, the Counties of Rockland, Suffolk and Westchester filed amended complaints in the U.S. District Court for the District of Massachusetts against approximately 50 pharmaceutical companies, including Mylan Labs, MPI and UDL, alleging violations of federal and state Medicaid laws, Medicaid and common law fraud, breach of contract, other New York statutes and regulations and unjust enrichment. Onondaga County, New York filed a substantially similar complaint in the U.S. District Court for the Northern District of New York in January 2005. In addition to the case filed by Onondaga County, New York, Mylan Labs, MPI and UDL have been named as defendants along with several dozen other drug manufacturers in lawsuits filed by 22 other counties in the State of New York in March 2005 and April 2005, asserting substantially similar claims to those asserted by Onondaga County. On January 26, 2005, the State of Alabama filed suit against 79 pharmaceutical companies, including Mylan Labs, MPI and UDL, in the Circuit Court of Montgomery County, Alabama, alleging that Alabama has been defrauded by false reporting of AWP, WAC and direct prices and asserts claims for fraud, wantonness and unjust enrichment, seeking compensatory and punitive damages and injunctive relief. In each case, the plaintiff seeks money damages and civil penalties in unspecified amounts and declaratory and injunctive relief, and in each matter Mylan Labs and its subsidiaries have not yet been required to respond to the complaint or the amended complaint, as applicable. The Company intends to defend these actions vigorously.

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.

*Shareholder Litigation*

On November 22, 2004, an individual purporting to be a Mylan Labs shareholder, filed a civil action in the Court of Common Pleas of Allegheny County, Pennsylvania, against Mylan Labs and all members of its Board of Directors alleging that the Board members had breached their fiduciary duties by approving the planned acquisition of King Pharmaceuticals, Inc. (King) and by declining to dismantle the Company's anti-takeover defenses to permit an auction of the Company to Carl Icahn or other potential buyers of the Company, and also alleging that certain transactions



between the Company and its directors (or their relatives or companies with which they were formerly affiliated) may have been wasteful. On November 23, 2004, a substantially identical complaint was filed in the same court by another purported Mylan Labs shareholder. The actions are styled as shareholder derivative suits on behalf of Mylan Labs and class actions on behalf of all Mylan Labs shareholders, and have been consolidated by the court under the caption In re Mylan Laboratories Inc. Shareholder Litigation. Mylan Labs and its directors filed preliminary objections seeking dismissal of the complaints. On January 19, 2005, the plaintiffs amended their complaints to add Bear Stearns & Co., Inc., Goldman Sachs & Co., Richard C. Perry, Perry Corp., American Stock Transfer & Trust Company, and John Does 1-100 as additional defendants, and to add claims regarding trading activity by the additional defendants and the implications on Mylan Labs shareholder rights agreement. The plaintiffs are seeking injunctive and declaratory relief and undisclosed damages. Mylan Labs and its directors have not yet been required to respond to the amended complaint.

**Table of Contents**

On December 10, 2004, High River Limited Partnership ( High River ), an entity controlled by Carl Icahn, filed suit in the U.S. District Court for the Middle District of Pennsylvania against Mylan Labs, its Vice Chairman and Chief Executive Officer Robert J. Coury, Richard C. Perry, Perry Corp. and John Does 1-100 , asserting against the Company a claim for violation of federal securities laws and against the Company and Mr. Coury a claim for alleged breaches of Pennsylvania statutory and common law, in connection with SEC filings and other public statements concerning the planned King acquisition. The complaint also asserts claims under the federal securities laws and Pennsylvania corporate law concerning a possible shareholder vote relating to the proposed merger. On January 27, 2005, the court granted a motion by defendants Perry Corp. and Mr. Perry to transfer the case to the U.S. District Court for the Southern District of New York. Mylan Labs, Mr. Coury and the other defendants have filed motions to dismiss the complaint in its entirety, which motions are currently pending before the court.

On February 22, 2005, High River filed a complaint naming Mylan Labs and its directors in the U.S. District Court for the Middle District of Pennsylvania challenging the validity under Pennsylvania law of amendments to the provisions of the Company s bylaws requiring shareholders to provide advance notice of nominations of directors for election at Mylan Labs annual meeting of shareholders. Icahn s High River sought a temporary restraining order ( TRO ) in an attempt to block implementation of the advance notice bylaw. The Court denied High River s motion for a TRO, and High River voluntarily withdrew the case without prejudice. On March 24, 2005, High River filed another complaint in the same court naming the same defendants and seeking substantially the same relief. Mylan has moved to dismiss the new action.

*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 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      |
| <b>Fiscal 2004</b> | <b>High</b> | <b>Low</b> |
| First quarter      | \$ 23.82    | \$ 17.07   |
| Second quarter     | 27.10       | 20.61      |
| Third quarter      | 28.53       | 20.00      |
| Fourth quarter     | 26.35       | 21.95      |

As of May 11, 2005, there were approximately 160,500 holders of record of our common stock, including those held in street or nominee name.

In the third quarter of fiscal 2003, the Company increased the quarterly cash dividend rate to 2.22 cents per share. In the third quarter of fiscal 2004, the Company's Board of Directors voted again to increase the quarterly dividend by 35% to 3.0 cents per share. 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.

**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.

(in thousands, except per share data)

| Fiscal year ended March 31,                 | 2005         | 2004         | 2003         | 2002         | 2001         |
|---|--------------|--------------|--------------|--------------|--------------|
| Statements of Earnings:                     |              |              |              |              |              |
| Total revenues                              | \$ 1,253,374 | \$ 1,374,617 | \$ 1,269,192 | \$ 1,104,050 | \$ 846,696   |
| Cost of sales                               | 629,834      | 612,149      | 597,756      | 480,111      | 464,521      |
| Gross profit                                | 623,540      | 762,468      | 671,436      | 623,939      | 382,175      |
| Operating expenses:                         |              |              |              |              |              |
| Research and development                    | 87,881       | 100,813      | 86,748       | 58,847       | 64,385       |
| Selling and administrative                  | 259,478      | 201,612      | 173,070      | 169,913      | 151,212      |
| Litigation settlements, net                 | (25,990)     | (34,758)     | (2,370)      |              | 147,000      |
| Earnings from operations                    | 302,171      | 494,801      | 413,988      | 395,179      | 19,578       |
| Other income, net                           | 10,076       | 17,807       | 12,525       | 13,144       | 38,435       |
| Earnings before income taxes                | 312,247      | 512,608      | 426,513      | 408,323      | 58,013       |
| Provision for income taxes                  | 108,655      | 177,999      | 154,160      | 148,072      | 20,885       |
| Net earnings                                | \$ 203,592   | \$ 334,609   | \$ 272,353   | \$ 260,251   | \$ 37,128    |
|   |              |              |              |              |              |
| March 31,                                   | 2005         | 2004         | 2003         | 2002         | 2001         |
| Selected balance sheet data:                |              |              |              |              |              |
| Total assets                                | \$ 2,135,673 | \$ 1,885,061 | \$ 1,745,223 | \$ 1,619,880 | \$ 1,472,500 |
| Working capital                             | 1,282,945    | 1,144,073    | 962,440      | 891,598      | 589,955      |
| Long-term obligations                       | 19,325       | 19,130       | 19,943       | 23,883       | 25,263       |
| Total shareholders' equity                  | 1,845,936    | 1,659,788    | 1,446,332    | 1,402,239    | 1,132,536    |
| Per common share data:                      |              |              |              |              |              |
| Net earnings:                               |              |              |              |              |              |
| Basic                                       | \$ 0.76      | \$ 1.24      | \$ 0.98      | \$ 0.92      | \$ 0.13      |
| Diluted                                     | \$ 0.74      | \$ 1.21      | \$ 0.96      | \$ 0.91      | \$ 0.13      |
| Shareholders' equity diluted                | \$ 6.75      | \$ 6.01      | \$ 5.12      | \$ 4.89      | \$ 3.97      |
| Cash dividends declared and paid            | \$ 0.12      | \$ 0.10      | \$ 0.08      | \$ 0.07      | \$ 0.07      |
| Weighted average common shares outstanding: |              |              |              |              |              |
| Basic                                       | 268,985      | 268,931      | 278,789      | 282,432      | 283,023      |
| Diluted                                     | 273,621      | 276,318      | 282,330      | 286,578      | 285,186      |

*In fiscal years 2005, 2004 and 2003, we settled various outstanding legal matters for a net gain of \$25,990, \$34,758 and \$2,370, respectively. In fiscal 2001, we reached a tentative settlement with the Federal Trade Commission, States Attorneys General and certain private parties with regard to lawsuits filed against the Company relating to*

*lorazepam and clorazepate in the amount of \$147,000. This settlement was approved by the court and made final in February 2002.*

**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 twelve-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, will, 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 1. 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 and brand pharmaceutical products. Fiscal year 2005 net revenues topped \$1.0 billion for the fourth consecutive year at \$1.25 billion. Our Generic Segment also achieved \$1.0 billion in net revenues for the third consecutive year, realizing sales of \$1.01 billion. Our Brand Segment recorded net revenues of \$240.9 million.

For fiscal 2004, total revenues were \$1.37 billion, comprised of Generic Segment net revenues of \$1.10 billion and Brand Segment revenues of \$278.5 million. Year over year, this represents a decrease of 9% in total revenues, 8% in the Generic Segment and 14% in the Brand Segment.

The decrease in revenues during fiscal 2005 is due in part to the absence of a significant new product launch until the fourth quarter of fiscal 2005. In January 2005, Mylan launched its fentanyl transdermal system (fentanyl), the generic equivalent of Alza Corporation's Duragesic®. Conversely, in the prior year, omeprazole was launched in August 2003 and contributed significantly to revenue for the final eight months of fiscal 2004. In total, Mylan realized \$134.6 million in revenue from products launched in fiscal 2004, compared to \$87.3 million from products launched during fiscal 2005.

Consolidated gross profit for fiscal 2005 was \$623.5 million compared to \$762.5 million in the prior year, a decrease of 18%, while gross margins decreased from 55.5% to 49.7%. Operating income decreased by 39% to \$302.2 million in fiscal 2005, compared to \$494.8 million in fiscal 2004. These decreases were realized by both the Generic and the Brand Segments.

For the Generic Segment, gross profit decreased by 18% to \$489.8 million and gross margins decreased from 54.8% to 48.4%. Generic Segment operating income decreased by 24% to \$386.2 million. Brand Segment gross profit for fiscal 2005 was \$133.8 million, a decrease of 18%, and gross margins decreased to 55.5% from 58.2%. Brand Segment operating income decreased by 24% to \$35.4 million.

Net earnings for fiscal 2005 were \$203.6 million compared to \$334.6 million in fiscal 2004, a decrease of 39%. Earnings per diluted share decreased from \$1.21 in fiscal 2004 to \$0.74 in fiscal 2005. A more thorough discussion of operating results by segment is provided under the heading Results of Operations.

Other factors which impacted the results of fiscal 2005 were:

**Termination of King Acquisition** On July 23, 2004, we entered into an Agreement and Plan of Merger ( Agreement ) to acquire King Pharmaceuticals, Inc. ( King ) in a stock-for-stock transaction. On February 27, 2005, Mylan and King announced that the companies had mutually agreed to terminate the Agreement. Following the termination of the Agreement, in the fourth quarter of fiscal 2005, Mylan recorded expenses in the amount of approximately \$18.3 million for costs directly related to the terminated acquisition. An additional \$4.6 million of expenses were incurred during fiscal 2005 consisting of consulting costs related to the planned integration of the two companies. In all, these expenses reduced diluted earnings per share for fiscal 2005 by approximately \$0.06.

**Table of Contents**

**Competition on omeprazole subsequent to launch** During the past year, additional generic competition has entered the omeprazole market. In general, additional generic competition usually results in lower pricing and volume. Competition caused significantly lower pricing on omeprazole sales compared to the prior year, during which the product was launched. However, we achieved higher volumes due primarily to expanding our customer base which helped to partially offset the impact of the unfavorable pricing. In addition to other generics, Mylan faced competition on omeprazole from an over-the-counter product and other competing branded products.

**Competition on carbidopa/levodopa** For the past several years, Mylan had been the only generic market entrant for carbidopa/levodopa. During fiscal 2005, however, several additional generic competitors launched their bioequivalent version of carbidopa/levodopa. Similar to omeprazole, this additional competition has had negative implications on pricing as well as volume related to carbidopa/levodopa sales.

**Unexpected delay of fentanyl launch** In the third quarter of fiscal 2004, Mylan received final approval from the Food & Drug Administration ( FDA ) for fentanyl. Mylan was, therefore, prepared to launch this product upon patent expiration in July 2004. However, the FDA in June 2004, rescinded Mylan's final Abbreviated New Drug Application ( ANDA ) approval. The actions of the FDA prevented Mylan from launching fentanyl in July 2004, which was expected to contribute significantly to fiscal 2005 net revenues and net earnings. On January 28, 2005, the FDA granted Mylan final approval for fentanyl, following the denial of the pending citizen's petitions. Mylan launched the product immediately after receiving this approval. However, the pre-marketing of fentanyl by certain competitors, who represented that they would be in the market at market formation, despite not having a tentative or final approval from the FDA, coupled with strategies used by the authorized generic, caused what the Company believes was irrational pricing of fentanyl at market formation, thereby significantly reducing the revenue and profit which Mylan believes it could have earned from sales of this product. Mylan believes that there could be further price erosion as additional competitors enter the fentanyl market.



**Table of Contents**

**Authorized generics** In addition to the impact that authorized generics had on sales of fentanyl as discussed above, in late March 2004, Mylan launched nitrofurantoin monohydrate/macrocrystals capsules, the generic equivalent of Procter & Gamble's Macrobid®. As the first company to file a Paragraph IV certification, Mylan was entitled to a 180-day period of market exclusivity. However, Procter & Gamble entered into an agreement with another generic company to market Macrobid as an authorized generic which was launched immediately after the launch of Mylan's product, effectively eliminating Mylan's 180-day exclusivity period and significantly reducing the profit potential of this product to Mylan. Mylan has since filed a lawsuit against Procter & Gamble and its generic partner, on the grounds that this practice violates the law and undermines the Waxman-Hatch legislation which provides an incentive and various rights to a company that successfully challenges patents. Mylan also filed a citizen's petition with the FDA with respect to this issue.

**Regulatory action surrounding launch of levothyroxine sodium** Mylan submitted an ANDA for levothyroxine sodium as a bioequivalent generic product to Jones Pharma Inc.'s Levoxyl® and believed it held first-to-file status which, upon approval, would have given Mylan a 6-month period of marketing exclusivity. In addition, Mylan was the only applicant to submit an ANDA to market a generic equivalent of Abbott Laboratories' Synthroid®. However, due to the approval of supplemental NDAs for other previously marketed levothyroxine sodium products demonstrating bioequivalence to Synthroid and Levoxyl, the FDA allowed competing companies to market their levothyroxine sodium products as generic equivalents to Synthroid and Levoxyl prior to Mylan's approvals, effectively eliminating Mylan's 6-month exclusivity period. We believe that this resulted in the loss of significant potential market share for Mylan's product.

Despite the negative impact of competition, including authorized generics, on certain products during fiscal 2005, as well as decisions of the FDA and the courts, fiscal 2005 did contain many significant positive developments.

In addition to Mylan's launch of fentanyl which, through mid-April 2005, had captured approximately 60% of the generic market, and over 40% of the total market for this product, the following occurred during the year:

**Acceptance for filing of nebivolol NDA** During the second quarter of fiscal 2005, Mylan announced that the FDA accepted for filing its brand subsidiary's New Drug Application (NDA) for nebivolol, for which the Company is seeking approval for use in the management of hypertension.

**Launch of Apokyn** During the second quarter of fiscal 2005, Mylan launched Apokyn, which has been approved for the acute, intermittent treatment of hypomobility, off episodes associated with advanced Parkinson's disease. Apokyn, which has orphan drug status, has been studied as an adjunct to other medications.

**EMSAM** In December 2004, Somerset Pharmaceuticals, Inc. (Somerset), in which Mylan owns a 50% equity interest, entered into an agreement with Bristol-Myers Squibb for the commercialization and distribution of Somerset's EMSAM (selegiline transdermal system). Somerset received an Approvable letter from the FDA for EMSAM in February 2004, and if approved by the FDA, EMSAM would be the first transdermal treatment for major depressive disorder.

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

The following table presents the results of operations for each of our business segments at March 31:

| <i>(in thousands)</i>       | 2005         | Fiscal<br>2004 | 2003         |
|-----------------------------|--------------|----------------|--------------|
| <b>Consolidated:</b>        |              |                |              |
| Total revenues              | \$ 1,253,374 | \$ 1,374,617   | \$ 1,269,192 |
| Gross profit                | 623,540      | 762,468        | 671,436      |
| Research and development    | 87,881       | 100,813        | 86,748       |
| Selling and marketing       | 79,838       | 74,625         | 65,625       |
| General and administrative  | 179,640      | 126,987        | 107,445      |
| Litigation settlements, net | (25,990)     | (34,758)       | (2,370)      |
| Earnings from operations    | 302,171      | 494,801        | 413,988      |
| Other income, net           | 10,076       | 17,807         | 12,525       |
| Pretax earnings             | 312,247      | 512,608        | 426,513      |
| <b>Generic Segment:</b>     |              |                |              |
| Total revenues              | 1,012,503    | 1,096,128      | 1,012,617    |
| Gross profit                | 489,755      | 600,280        | 531,106      |
| Research and development    | 68,858       | 59,066         | 44,562       |
| Selling and marketing       | 12,353       | 11,707         | 11,160       |
| General and administrative  | 22,345       | 18,686         | 21,341       |
| Earnings from operations    | 386,199      | 510,821        | 454,043      |
| <b>Brand Segment:</b>       |              |                |              |
| Total revenues              | 240,871      | 278,489        | 256,575      |
| Gross profit                | 133,785      | 162,188        | 140,330      |
| Research and development    | 19,023       | 41,747         | 42,186       |
| Selling and marketing       | 67,485       | 62,918         | 54,465       |
| General and administrative  | 11,898       | 11,002         | 10,997       |
| Earnings from operations    | 35,379       | 46,521         | 32,682       |
| <b>Corporate/Other:</b>     |              |                |              |
| General and administrative  | 145,397      | 97,299         | 75,107       |
| Litigation settlements, net | (25,990)     | (34,758)       | (2,370)      |
| Other income, net           | 10,076       | 17,807         | 12,525       |

*Segment net revenues represent revenues from unrelated third parties. For the Generic and Brand Segments, earnings from operations represent segment gross profit less direct research and development, selling and marketing, and general and administrative expenses. Corporate/Other includes certain general and administrative expenses, such as legal expenditures, litigation settlements and non-operating income and expense.*

**Table of Contents**

**Fiscal 2005 Compared to Fiscal 2004**

*Revenues and Gross Profit*

Revenues for fiscal 2005 were \$1.25 billion compared to \$1.37 billion for fiscal 2004, a decrease of \$121.2 million or 9%. 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, 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, 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 revenues during fiscal 2005 was realized by both the Generic Segment and the Brand Segment. Generic Segment net revenues totaled \$1.01 billion for fiscal 2005 compared to \$1.10 billion in fiscal 2004, a decrease of \$83.6 million or 8%. For the Brand Segment revenues decreased \$37.6 million or 14% from \$278.5 million in fiscal 2004 to \$240.9 million in fiscal 2005.

Within the Generic Segment, the decrease in 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 carbidopa/levodopa, as well as 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 who 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, Generic volume shipped for the year increased nearly 6% to 11.4 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.

Revenues for the Brand Segment were also significantly impacted by pricing pressures as a result of additional competition. During fiscal 2005, Amnesteem and Digitek® were the two products most affected.

Fiscal 2004 Brand Segment revenues include \$13.9 million from the sale of the U.S. and Canadian rights for sertaconazole nitrate 2% cream (sertaconazole). Excluding the sertaconazole sale and revenue from new products, volume for the Brand Segment was consistent year over year.

## Edgar Filing: MYLAN LABORATORIES INC - Form 10-K

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. For the Generic Segment, gross profit for fiscal 2005 decreased by \$110.5 million to \$489.8 million from \$600.3 million in fiscal 2004, and decreased as a percentage of revenues from 54.8% to 48.4%. The decrease in Generic Segment 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.

Brand Segment gross profit for fiscal 2005 decreased \$28.4 million to \$133.8 million from \$162.2 million in fiscal 2004 and decreased as a percentage of revenues from 58.2% to 55.5%. Excluding the sertaconazole sale, Brand Segment margins were essentially unchanged.

## **Table of Contents**

### *Research and Development*

Research and development ( 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%. Brand Segment R&D expense decreased by \$22.7 million or 54% to \$19.0 million in fiscal 2005 from \$41.7 million in fiscal 2004. This decrease was partially offset by an increase of \$9.8 million or 17% to \$68.9 million from \$59.1 million in R&D expense in the Generic Segment.

The decrease in Brand Segment R&D expense is due to the completion, in late fiscal 2004, of clinical studies related to nebivolol, a product for the treatment of hypertension. The NDA for nebivolol was submitted to the FDA on April 30, 2004, and accepted for filing by the FDA on June 29, 2004. As clinical development programs for other products and life cycle management studies are initiated, it is expected that Brand Segment R&D expenses will increase in future periods.

The increase in Generic Segment R&D expense is due equally to an increase in payroll and payroll related costs and the cost of ongoing generic studies. The increase in generic studies is the result of both a higher number of subjects per study and an increase in the related raw material costs. 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.

### *Selling and Marketing*

Selling and marketing expense for fiscal 2005 was \$79.8 million compared to \$74.6 million in fiscal 2004, an increase of \$5.2 million or 7%. This increase was driven by the Brand Segment for which selling and marketing expense increased by \$4.6 million or 7% to \$67.5 million. This increase was primarily the result of costs incurred with respect to nebivolol and costs associated with the fiscal 2005 launch of Apokyn.

### *General and Administrative*

General and administrative ( G&A ) expense was \$179.6 million in fiscal 2005, an increase of \$52.7 million or 41% from \$127.0 million in fiscal 2004. The majority of the increase, or \$48.1 million, is the result of higher Corporate expenses. The Generic Segment, which increased by \$3.7 million from fiscal 2004, accounted for the remainder of the increase in G&A expense.

Included in Corporate G&A expense for fiscal 2005 is approximately \$18.3 million of costs 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 G&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 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

## **Table of Contents**

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 has temporarily ceased recording losses on this investment.

Somerset is engaged in the manufacturing and marketing of Eldepryl® (selegiline), its sole commercial product, which is used for the treatment of patients with late-stage Parkinson's disease. During fiscal 2004, Somerset received an Approvable letter from the FDA with regard to EMSAM (selegiline transdermal system), the transdermal therapy for which it is seeking an indication for the treatment of major depressive disorder. As Somerset continues its research and development activities, including working with the FDA to obtain approval for EMSAM, its earnings may continue to be adversely affected.

### *Income Taxes*

The effective tax rate for fiscal 2005 was 34.8% compared to 34.7% for fiscal 2004.

## **Fiscal 2004 Compared to Fiscal 2003**

### *Revenues and Gross Profit*

Revenues for fiscal 2004 were \$1.37 billion compared to \$1.27 billion for fiscal 2003, an increase of 8% or \$105.4 million. Both the Generic Segment and the Brand Segment contributed to the overall increase in revenues. Revenues for the Generic Segment, which accounted for approximately 80% of consolidated revenues, increased \$83.5 million or 8% over the prior year while Brand Segment revenues increased \$21.9 million or 9% over the prior year.

Generic Segment net revenues exceeded \$1.0 billion for the second time in the Company's history, reaching \$1.10 billion compared to \$1.01 billion in fiscal 2003. The increase in net revenues is primarily the result of new products launched in fiscal 2004, which contributed net revenues of \$134.6 million, largely due to omeprazole. Relatively stable pricing on existing products also contributed to the increase in Generic Segment net revenues. These increases were partially offset by lower volume. Generic volume shipped was approximately 10.8 billion doses in fiscal 2004 compared to 11.6 billion doses in fiscal 2003. Our focus is to maximize gross margins within our product portfolio which may result in fluctuations in volume and changes to our product mix. Following the entrance into the market of generic competition, both price and volume erosion may occur in the pharmaceutical industry which could adversely affect products in our portfolio.

Revenues for the Brand Segment benefited from a full year of Amnesteem sales. The Brand Segment generated revenues of \$278.5 million, an increase of \$21.9 million or 9% over fiscal 2003. Amnesteem, which was launched in the third quarter of fiscal 2003, contributed revenues of \$75.9 million in fiscal 2004, an increase of 24% over the prior year. Also contributing to the increase in revenues is \$13.9 million realized from the sertaconazole sale recorded under the caption Other Revenue. Product sales, as well as sales of the rights to pharmaceutical products, are included in revenues as such sales are a normal part of our operations.

For Amnesteem, significant price erosion was experienced in fiscal 2004 due to the entrance into the market of other generic competitors. This was compensated for, however, by increased volume as Amnesteem held its position

as market leader, maintaining an overall market share of approximately 43% into May of 2004. Increased competition resulted in price erosion and lower volume on Acticin®, Digitek and Maxzide® during fiscal 2004 while other products in the portfolio, primarily phenytoin and Phenytek , experienced both favorable pricing and increased volume.

Consolidated gross profit for fiscal 2004 was \$762.5 million, or 56% of revenues, compared to \$671.4 million, or 53% of revenues in fiscal 2003. For the Generic Segment, gross profit for fiscal 2004 increased by \$69.2 million to \$600.3 million from \$531.1 million in fiscal 2003 and increased as a percentage of revenues from 52% to 55%. The increase is primarily due to higher margins contributed by new products, primarily omeprazole. Additionally, a slight overall increase in gross margin was realized by the Generic Segment's existing products as a result of favorable product mix.

Brand Segment gross profit for fiscal 2004 increased \$21.9 million to \$162.2 million from \$140.3 million in fiscal 2003



## **Table of Contents**

and increased as a percentage of revenues from 55% to 58%, primarily as a result of favorable pricing realized on several core products and the sertaconazole sale for which there were minimal associated costs in fiscal 2004. This increase was realized despite the fact that sales of Amnesteem contribute lower gross margins than the majority of the Brand Segment's other core products due to royalties paid under a supply and distribution agreement.

### *Research and Development*

R&D expense for fiscal 2004 was \$100.8 million or approximately 7% of revenues compared to \$86.7 million or 7% of revenues in fiscal 2003, which represents an increase of \$14.1 million or 16%. The increase was primarily attributable to the Generic Segment, for which R&D expense increased \$14.5 million or 33%, partially offset by a slight decrease in the Brand Segment of \$0.4 million or 1%.

The increase in the Generic Segment R&D expense is due equally to increased R&D headcount, as well as an increase in the amount and timing of current and future ANDA submissions, which resulted in increased study costs.

The decrease in the Brand Segment R&D expense is due to the completion, during fiscal 2004, of clinical studies primarily related to nebivolol, a product for the treatment of hypertension. These studies had been fully enrolled in the prior year.

### *Selling and Marketing*

Selling and marketing expense for fiscal 2004 was \$74.6 million compared to \$65.6 million in fiscal 2003. As a percentage of revenues, selling and marketing expense approximated 5% in both years. Generic Segment selling and marketing expense for fiscal 2004 increased \$0.5 million or 5% to \$11.7 million from \$11.2 million. Brand Segment selling and marketing expense increased \$8.5 million or 16% to \$62.9 million in fiscal 2004 from \$54.5 million in fiscal 2003. This increase was primarily the result of pre-marketing costs associated with the upcoming launch of Apokyn.

### *General and Administrative*

G&A expense was \$127.0 million in fiscal 2004, an increase of \$19.5 million or 18% from \$107.4 million in fiscal 2003. G&A expenses approximated 9% of revenues in both years. The increase in G&A expense is the result of increased Corporate expenses, partially offset by lower expenses in the Generic Segment.

Generic Segment G&A expense decreased \$2.7 million or 12% to \$18.7 million in fiscal 2004. Brand Segment G&A expenses remained constant at \$11.0 million for fiscal years 2004 and 2003.

Corporate G&A expense for fiscal 2004 was \$97.3 million compared to \$75.1 million in fiscal 2003, an increase of \$22.2 million or 30%. This increase is primarily due to increased legal expenses related to ongoing as well as recently settled litigation. Successful defense of patent infringement claims, including Paragraph IV challenges, is an integral part of our ability to continue to deliver pharmaceutical products to the market.

### *Litigation Settlements*

Net gains of \$34.8 million were recorded in fiscal 2004 with respect to the settlement of various lawsuits. Of this, \$12.5 million was related to a settlement reached with respect to the marketing and manufacturing of Zagam, and \$10.2 million was related to a 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. This \$10.0 million represents a partial reimbursement of the settlement funds

paid by Mylan toward the settlement announced in fiscal 2003. These additional payments were agreed to by the co-defendants, and the settlement received final approval from the judge overseeing the litigation during fiscal 2004.

*Other Income, Net*

Other income, net of other expenses, was \$17.8 million in fiscal 2004 compared to \$12.5 million in fiscal 2003. This increase of \$5.3 million is primarily the result of a \$5.0 million gain on the sale of an office building recorded in fiscal 2004, partially offset by a greater loss recorded on our investment in Somerset. In addition, fiscal 2003 included a \$5.7 million impairment charge recorded on an investment which Mylan held in a foreign entity.

## **Table of Contents**

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 2004 was \$7.1 million compared to a loss of \$4.6 million in fiscal 2003. Additionally in fiscal 2004, Mylan received dividends totaling \$10.0 million.

### *Income Taxes*

The effective tax rate for fiscal 2004 was 34.7% compared to 36.1% for fiscal 2003. The decrease in the effective tax rate was primarily due to the benefit of expansion tax credits received from certain states and other economic incentives awarded by the government of Puerto Rico.

## **Liquidity and Capital Resources**

The Company's primary source of liquidity continues to be cash flows from operating activities, which were \$203.7 million for fiscal 2005. Working capital as of March 31, 2005, was \$1.28 billion, an increase of \$138.9 million from the balance at March 31, 2004. The majority of this increase was the result of higher marketable securities, and an increase in net accounts receivable and net deferred tax assets, partially offset by lower inventories, higher accounts payable and income taxes payable and a decrease in other current assets.

The increase in accounts receivable at March 31, 2005, is primarily the result of sales of fentanyl which was launched during the fourth quarter of fiscal 2005. The increase in estimated sales allowances netted against accounts receivable also increased primarily as a result of the launch of fentanyl. See *Application of Critical Accounting Policies* for further discussion of estimated sales allowances. Net deferred tax assets increased primarily as a result of future tax benefits related to the increase in provisions for estimated sales allowances.

The decrease in inventory is the result of lower inventories carried with respect to certain products, such as omeprazole, and is reflective of the corresponding decrease in revenues from these products. This decrease is also reflective of the overall increase in volume shipped during fiscal 2005, due in part to new product launches, primarily fentanyl. In the prior year, inventory at March 31, 2004, increased from March 31, 2003, due to new product launches and planned production increases in order to meet forecasted demand.

The increase in accounts payable is the result of the change in the amount of outstanding checks in excess of cash in our primary disbursement accounts. See discussion of financing activities below. Income taxes payable increased from March 31, 2004, to March 31, 2005, primarily as a result of the timing of estimated tax payments. Other current assets decreased primarily as a result of the receipt of \$10.0 million from the fiscal 2004 sale of the Company's investment in a foreign entity, and the receipt of \$17.0 million related to lawsuits settled in prior periods.

In addition to the receipt of the \$17.0 million from lawsuits settled in prior periods, during the first quarter of fiscal 2005, Mylan received approximately \$35.0 million related to the settlement of certain patent litigation claims involving omeprazole.

In fiscal 2005, Mylan paid \$9.0 million to resolve all pending litigation with respect to paclitaxel. In fiscal 2004 payments of \$32.6 million were made related to two lawsuits which were settled during fiscal 2003.

Cash used in investing activities during fiscal 2005 was \$174.9 million. Of the Company's \$2.1 billion of total assets at March 31, 2005, \$778.7 million was held in cash, cash equivalents and marketable securities. Investments in marketable securities consists 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 2005 were \$90.7 million. These expenditures were incurred primarily with respect to the Company's planned expansions. Due to the timing of the completion of certain phases of the Company's previously announced expansion and ERP implementation, certain capital expenditures which had originally been forecasted for fiscal 2005, will now be expended in fiscal 2006. Additionally, the Company expects the majority of the expenditures related to the ERP implementation to occur in fiscal 2006 and fiscal 2007. Including the effect of these items, capital expenditures for fiscal 2006 are expected to be approximately \$120 million.

Cash used in financing activities was \$2.6 million for fiscal 2005. Included in financing activities in the prior year was \$133.1 million used to purchase shares of the Company's stock under a stock repurchase program. This program was

**Table of Contents**

completed on November 18, 2003. Also included in financing activities in fiscal 2005 was a \$19.6 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.

In the third quarter of fiscal 2004, the Company's Board of Directors voted to increase the quarterly dividend 35% to 3.0 cents per share. Dividend payments totaled \$32.3 million during fiscal 2005.

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 the Company upon the attainment of specified milestones. While these arrangements help to reduce the financial risk for unsuccessful projects, fulfillment of specified milestones or the occurrence of other obligations may result in fluctuations in cash flows from operating activities.

In order to provide additional operating leverage, if necessary, the Company maintains a revolving line of credit with a commercial bank providing for borrowings of up to \$50.0 million (see Note 7 to the Consolidated Financial Statements). As of March 31, 2005, no funds have been advanced under this line of credit. Additionally, the Company is continuously evaluating initiatives as a strategic part of its future growth, which may include; stock repurchase programs, and the potential acquisition of products, as well as companies. Consequently, the Company may utilize current cash reserves or incur additional indebtedness to finance any such strategic initiatives, which could impact future liquidity.

**Contractual Obligations**

The following table summarizes our contractual obligations at March 31, 2005 and the effect that such obligations are expected to have on our liquidity and cash flows in future periods:

|  | Total     | Less<br>than<br>One<br>Year | One -<br>Three<br>Years | Three -<br>Five<br>Years | Thereafter |
|--|-----------|-----------------------------|-------------------------|--------------------------|------------|
| As of March 31, 2005<br>(in thousands) |           |                             |                         |                          |            |
| Operating leases                       | \$ 13,977 | \$ 5,644                    | \$ 7,513                | \$ 604                   | \$ 216     |
| Long-term obligations                  | 19,325    | 1,821                       | 5,463                   | 3,642                    | 8,399      |
| Line of credit                         |           |                             |                         |                          |            |
| Letter of credit                       | 775       | 775                         |                         |                          |            |
|  | \$ 34,077 | \$ 8,240                    | \$ 12,976               | \$ 4,246                 | \$ 8,615   |

We lease certain real property under various operating lease arrangements that expire generally over the next four 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 sales force and key

employees.

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

We maintain a revolving line of credit with a commercial bank. This line of credit expires on July 31, 2005 and allows Mylan to borrow up to \$50.0 million on an unsecured basis, at an alternative base rate. At the Company's option, it may elect an interest rate based on the published daily London Interbank Offered Rate by giving written notice to the lender. The agreement does not contain any significant financial covenants. At March 31, 2005 and 2004, we had no outstanding borrowings under this line of credit.

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 to obtain rights to the use of the patent, through milestone payments, in exchange for marketing and distribution rights to the product. Because milestones represent

**Table of Contents**

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 \$9.3 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.

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 the presentation of our financial condition, changes in financial condition or results of operations. The Company has identified the following to be its critical accounting policies: the determination of revenue provisions; and the impact of existing legal matters. These critical accounting policies affect each of the operating segments.

*Revenue Provisions*

Revenue is 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 \$349.4 million and \$264.2 million at March 31, 2005 and 2004. Other current liabilities include \$51.8 million and \$28.2 million at March 31, 2005 and 2004, 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, 2005:

|                                     | Balance    | Checks/Credits | Provisions  | Balance    |
|-------------------------------------|------------|----------------|-------------|------------|
|                                     | March 31,  | Issued         | Recorded in | March 31,  |
|                                     | 2004       | to Third       | Current     | 2005       |
|                                     |            | Parties        | Period      |            |
| Chargebacks                         | \$ 133,784 | \$ (860,343)   | \$ 892,625  | \$ 166,066 |
| Customer performance and promotions | \$ 37,611  | \$ (162,939)   | \$ 195,130  | \$ 69,802  |

|         |    |        |    |          |    |        |    |        |
|---------|----|--------|----|----------|----|--------|----|--------|
| Returns | \$ | 45,311 | \$ | (35,955) | \$ | 37,188 | \$ | 46,544 |
|---------|----|--------|----|----------|----|--------|----|--------|

The accrual for chargebacks increased primarily as a result of chargebacks related to sales of fentanyl in the fourth quarter of fiscal 2005 and continued price erosion on the Company's existing portfolio. This increase was partially offset by certain customers reducing the amount of inventory they have on their shelves at year end compared to the prior year. No material amounts included in the provision for chargebacks recorded in the current period relate to prior periods. Direct rebates from sales of fentanyl and promotions offered to customers with respect to the fentanyl launch also accounted for the majority of the increase in the accrual for customer performance and promotions.



**Table of Contents**

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

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

*Returns* Consistent with industry practice, we maintain a return policy that allows our customers to return product within a specified period prior to and subsequent to the expiration date. Our estimate of the provision for returns is based upon our historical experience with actual returns, which is applied to the level of sales for the period that corresponds to the period during which our customers may return product. This period is known by us based on the shelf lives of our products at the time of shipment. Additionally, we consider factors such as levels of inventory in the distribution channel, product dating and expiration period, size and maturity of the market prior to a product launch, entrance in the market of additional generic competition, changes in formularies or launch of 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 which 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 Company's financial position or results of operations, such estimates are considered to be critical accounting estimates. After review, it was determined at March 31, 2005 that for each of the various legal proceedings in which we are involved, the conditions mentioned above were not met. The Company will

**Table of Contents**

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 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. In April 2005, the SEC delayed the effective date of SFAS 123(R) to fiscal years beginning after June 15, 2005. Management is currently assessing the impact that adoption of this Statement will have on the Company's Consolidated Financial Statements.

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

The Company is subject to market risk primarily from changes in the market values of investments in marketable debt and equity securities. Additional 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. Professional portfolio managers manage the majority of our investments.

The following table summarizes the investments in marketable debt and equity securities which subject the Company to market risk at March 31, 2005 and 2004:

| <i>(in thousands)</i>        | 2005       | 2004       |
|------------------------------|------------|------------|
| Marketable debt securities   | \$ 667,170 | \$ 581,212 |
| Marketable equity securities | 3,178      | 4,233      |
|                              | \$ 670,348 | \$ 585,445 |

*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. The investment policy limits investments to certain types of instruments issued by institutions and government agencies with investment-grade credit ratings. Of the \$667.2 million invested in marketable debt securities at March 31, 2005, \$163.2 million will mature within one year. This short duration to maturity creates minimal exposure to fluctuations in market values for these investments. A significant change in current interest rates could affect the market value of the remaining \$504.0 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 \$25.2 million change in marketable debt securities.

**Table of Contents**

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

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

|   | <b>Page</b> |
|---|-------------|
| <u>Consolidated Balance Sheets as of March 31, 2005 and 2004</u>  | 39          |
| <u>Consolidated Statements of Earnings for the fiscal years ended March 31, 2005, 2004 and 2003</u>             | 40          |
| <u>Consolidated Statements of Shareholders' Equity for the fiscal years ended March 31, 2005, 2004 and 2003</u> | 41          |
| <u>Consolidated Statements of Cash Flows for the fiscal years ended March 31, 2005, 2004 and 2003</u>           | 42          |
| <u>Notes to Consolidated Financial Statements</u>   | 43          |
| <u>Management's Report on Internal Control over Financial Reporting</u>   | 60          |
| <u>Reports of Independent Registered Public Accounting Firm</u>   | 61          |
| <u>Supplementary Financial Information</u>  | 63          |

**Table of Contents****Mylan Laboratories Inc.****Consolidated Balance Sheets**

(in thousands, except share and per share data)

| March 31,                                       | 2005         | 2004         |
|---|--------------|--------------|
| Assets  |              |              |
| Current assets:                                 |              |              |
| Cash and cash equivalents                       | \$ 137,733   | \$ 111,484   |
| Marketable securities                           | 670,348      | 585,445      |
| Accounts receivable, net                        | 297,334      | 191,094      |
| Inventories                                     | 286,267      | 320,797      |
| Deferred income tax benefit                     | 119,327      | 78,477       |
| Prepaid expenses and other current assets       | 17,443       | 40,315       |
| Total current assets                            | 1,528,452    | 1,327,612    |
| Property, plant and equipment, net              | 336,719      | 273,051      |
| Intangible assets, net                          | 120,493      | 134,601      |
| Goodwill  | 102,579      | 102,579      |
| Other assets                                    | 47,430       | 47,218       |
| Total assets                                    | \$ 2,135,673 | \$ 1,885,061 |
| Liabilities and shareholders' equity            |              |              |
| Liabilities                                     |              |              |
| Current liabilities:                            |              |              |
| Trade accounts payable                          | \$ 78,114    | \$ 50,410    |
| Income taxes payable                            | 44,123       | 23,837       |
| Current portion of long-term obligations        | 1,586        | 1,586        |
| Cash dividends payable                          | 8,078        | 8,052        |
| Other current liabilities                       | 113,606      | 99,654       |
| Total current liabilities                       | 245,507      | 183,539      |
| Long-term obligations                           | 19,325       | 19,130       |
| Deferred income tax liability                   | 24,905       | 22,604       |
| Total liabilities                               | 289,737      | 225,273      |
| 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 2005 and 2004 |              |              |

Edgar Filing: MYLAN LABORATORIES INC - Form 10-K

|  |              |              |
|--|--------------|--------------|
| Shares issued: 304,434,724 in 2005 and 303,553,121 in 2004 | 152,217      | 151,777      |
| Additional paid-in capital                                 | 354,172      | 338,143      |
| Retained earnings  | 1,808,802    | 1,637,497    |
| Accumulated other comprehensive earnings                   | 870          | 2,496        |
|  | 2,316,061    | 2,129,913    |
| Less treasury stock at cost                                |              |              |
| Shares: 35,129,643 in 2005 and 2004                        | 470,125      | 470,125      |
| Total shareholders equity                                  | 1,845,936    | 1,659,788    |
| Total liabilities and shareholders equity                  | \$ 2,135,673 | \$ 1,885,061 |

*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,                 | 2005         | 2004         | 2003         |
|---|--------------|--------------|--------------|
| Revenues:                                   |              |              |              |
| Net revenues                                | \$ 1,253,374 | \$ 1,360,707 | \$ 1,269,192 |
| Other revenue                               |              | 13,910       |              |
| Total revenues                              | 1,253,374    | 1,374,617    | 1,269,192    |
| Cost of sales                               | 629,834      | 612,149      | 597,756      |
| Gross profit                                | 623,540      | 762,468      | 671,436      |
| Operating expenses:                         |              |              |              |
| Research and development                    | 87,881       | 100,813      | 86,748       |
| Selling and marketing                       | 79,838       | 74,625       | 65,625       |
| General and administrative                  | 179,640      | 126,987      | 107,445      |
| Litigation settlements, net                 | (25,990)     | (34,758)     | (2,370)      |
| Earnings from operations                    | 302,171      | 494,801      | 413,988      |
| Other income, net                           | 10,076       | 17,807       | 12,525       |
| Earnings before income taxes                | 312,247      | 512,608      | 426,513      |
| Provision for income taxes                  | 108,655      | 177,999      | 154,160      |
| Net earnings                                | \$ 203,592   | \$ 334,609   | \$ 272,353   |
| Earnings per common share:                  |              |              |              |
| Basic                                       | \$ 0.76      | \$ 1.24      | \$ 0.98      |
| Diluted                                     | \$ 0.74      | \$ 1.21      | \$ 0.96      |
| Weighted average common shares outstanding: |              |              |              |
| Basic                                       | 268,985      | 268,931      | 278,789      |
| Diluted                                     | 273,621      | 276,318      | 282,330      |

*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,  | 2005         | 2004         | 2003         |
|--|--------------|--------------|--------------|
| Common stock shares issued:  |              |              |              |
| Shares at beginning of year  | 303,553,121  | 300,904,262  | 297,451,189  |
| Fractional shares issued relative to the stock split   |              |              | 1,413        |
| Stock options exercised  | 881,603      | 2,648,859    | 3,451,660    |
| Shares at end of year  | 304,434,724  | 303,553,121  | 300,904,262  |
| Treasury stock:  |              |              |              |
| Shares at beginning of year  | (35,129,643) | (29,143,443) | (13,079,325) |
| Shares acquired upon the exercise of stock options   |              |              | (22,818)     |
| Issuance of restricted stock   |              | 472,500      |              |
| Stock purchases  |              | (6,458,700)  | (16,041,300) |
| Shares at end of year  | (35,129,643) | (35,129,643) | (29,143,443) |
| Common shares outstanding  | 269,305,081  | 268,423,478  | 271,760,819  |
| Common stock, \$0.50 par:  |              |              |              |
| Balance at beginning of year   | \$ 151,777   | \$ 150,452   | \$ 148,725   |
| Stock options exercised  | 440          | 1,325        | 1,727        |
| Balance at end of year   | 152,217      | 151,777      | 150,452      |
| Additional paid-in capital:  |              |              |              |
| Balance at beginning of year   | 338,143      | 304,350      | 267,094      |
| Fractional shares issued relative to the stock split   |              |              | 49           |
| Stock options exercised  | 9,628        | 25,342       | 29,035       |
| Issuance of restricted stock   |              | 5,656        |              |
| Unearned compensation  | 3,901        | (9,352)      |              |
| Tax benefit of stock option plans  | 2,500        | 12,159       | 8,172        |
| Other  |              | (12)         |              |
| Balance at end of year   | 354,172      | 338,143      | 304,350      |
| Retained earnings:   |              |              |              |
| Balance at beginning of year   | 1,637,497    | 1,330,933    | 1,080,736    |
| Net earnings   | 203,592      | 334,609      | 272,353      |
| Dividends declared (\$0.12 per share for fiscal 2005, \$0.10 per share for fiscal 2004 and \$0.08 per share for fiscal 2003) | (32,287)     | (28,045)     | (22,156)     |
| Balance at end of year   | 1,808,802    | 1,637,497    | 1,330,933    |



Edgar Filing: MYLAN LABORATORIES INC - Form 10-K

|  |              |              |              |
|--|--------------|--------------|--------------|
| Accumulated other comprehensive earnings:                    |              |              |              |
| Balance at beginning of year                                 | 2,496        | 3,718        | 7,920        |
| Net unrealized loss on marketable securities                 | (1,626)      | (1,222)      | (4,202)      |
| Balance at end of year                                       | 870          | 2,496        | 3,718        |
| Treasury stock, at cost:                                     |              |              |              |
| Balance at beginning of year                                 | (470,125)    | (343,121)    | (102,236)    |
| Shares acquired upon the exercise of stock options           |              |              | (344)        |
| Issuance of restricted stock                                 |              | 6,084        |              |
| Stock purchases  |              | (133,088)    | (240,541)    |
| Balance at end of year                                       | (470,125)    | (470,125)    | (343,121)    |
| Total shareholders' equity                                   | \$ 1,845,936 | \$ 1,659,788 | \$ 1,446,332 |
| Comprehensive earnings:                                      |              |              |              |
| Net earnings   | \$ 203,592   | \$ 334,609   | \$ 272,353   |
| Other comprehensive (loss) earnings, net of tax:             |              |              |              |
| Net unrealized holding (losses) gains on securities          | (1,711)      | 3,009        | 4,140        |
| Reclassification for losses (gains) included in net earnings | 85           | (4,231)      | (8,342)      |
| Other comprehensive loss, net of tax                         | (1,626)      | (1,222)      | (4,202)      |
| Comprehensive earnings                                       | \$ 201,966   | \$ 333,387   | \$ 268,151   |

*See Notes to Consolidated Financial Statements.*

**Table of Contents****Mylan Laboratories Inc.****Consolidated Statements of Cash Flows**

(in thousands)

| Fiscal year ended March 31,   | 2005       | 2004       | 2003       |
|---|------------|------------|------------|
| Cash flows from operating activities:   |            |            |            |
| Net earnings  | \$ 203,592 | \$ 334,609 | \$ 272,353 |
| Adjustments to reconcile net earnings to net cash provided from operating activities: |            |            |            |
| Depreciation and amortization   | 45,100     | 44,323     | 40,580     |
| Realized gain on sale of marketable securities  |            | (6,509)    | (12,829)   |
| Net loss from equity method investees   | 2,372      | 4,459      | 5,846      |
| Change in estimated sales allowances  | 108,778    | (24,016)   | 79,895     |
| Deferred income tax (benefit) expense   | (36,899)   | 32,275     | (22,025)   |
| Write-down of investments and intangible assets                                       |            |            | 7,571      |
| Gain on sale of building  |            | (5,000)    |            |
| Other non-cash items  | 7,951      | 765        | 3,214      |
| Receipts from (payments of) litigation settlements, net                               | 17,000     | (51,388)   | 28,616     |
| Cash received from Somerset   |            | 10,000     |            |
| Changes in operating assets and liabilities:  |            |            |            |
| Accounts receivable   | (192,799)  | 18,617     | (113,155)  |
| Inventories   | 34,530     | (83,020)   | (42,558)   |
| Trade accounts payable  | 8,082      | (25,378)   | 29,183     |
| Income taxes  | 22,010     | (11,096)   | 4,801      |
| Other operating assets and liabilities, net   | (16,006)   | (13,063)   | 31,651     |
| Net cash provided from operating activities   | 203,711    | 225,578    | 313,143    |
| Cash flows from investing activities:   |            |            |            |
| Proceeds from (purchase of):  |            |            |            |
| Capital assets  | (90,746)   | (118,451)  | (32,595)   |
| Reduction of investment in a limited liability partnership                            |            | 7,269      | 1,359      |
| Sale of assets  |            | 12,000     | 30         |
| Marketable securities   | (780,806)  | (793,539)  | (821,902)  |
| Sale of marketable securities   | 693,289    | 640,511    | 871,904    |
| Other items, net  | 3,372      | 1,884      | (2,528)    |
| Net cash (used in) provided from investing activities                                 | (174,891)  | (250,326)  | 16,268     |
| Cash flows from financing activities:   |            |            |            |
| Cash dividends paid   | (32,261)   | (26,024)   | (21,192)   |
| Increase in outstanding checks in excess of cash in disbursement accounts             | 19,622     | 9,771      |            |
| Purchase of common stock  |            | (133,088)  | (240,541)  |
| Proceeds from exercise of stock options   | 10,068     | 26,671     | 30,434     |

Edgar Filing: MYLAN LABORATORIES INC - Form 10-K

|  |            |            |            |
|--|------------|------------|------------|
| Net cash used in financing activities  | (2,571)    | (122,670)  | (231,299)  |
| Net increase (decrease) in cash and cash equivalents   | 26,249     | (147,418)  | 98,112     |
| Cash and cash equivalents beginning of year  | 111,484    | 258,902    | 160,790    |
| Cash and cash equivalents end of year  | \$ 137,733 | \$ 111,484 | \$ 258,902 |
| Supplemental disclosures of cash flow information:   |            |            |            |
| Cash paid during the year for:   |            |            |            |
| Income taxes   | \$ 123,725 | \$ 156,821 | \$ 171,382 |
| Non-cash investing activities:   |            |            |            |
| Marketable securities received from liquidation of investment in limited liability partnership | \$         | \$         | \$ 16,445  |
| Non-cash financing activities:   |            |            |            |
| Issuance of restricted stock   | \$         | \$ 11,740  | \$         |

*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 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.

**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 \$29,393,000 and \$9,771,000 at March 31, 2005 and 2004, 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 us 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 78% and 58% of the accounts receivable balances represent amounts due from four customers at March 31, 2005 and 2004. Total allowances for doubtful accounts were \$7,340,000 and \$5,965,000 at March 31, 2005 and 2004.

**Inventories.** Inventories are stated at the lower of cost or market, with cost determined by the first-in, first-out method. Provisions for potentially obsolete or slow-moving inventory 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 \$26,455,000, \$23,237,000 and \$20,780,000 for fiscal years 2005, 2004 and 2003, 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 includes property, plant and equipment and intangible assets with definite lives, are evaluated periodically in relation to the expected future cash

## **Table of Contents**

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 and undistributed earnings and losses.

Non-marketable equity investments for which we do not have the ability to exercise significant influence are accounted for using the cost method. Such investments are included in other assets on the balance sheet. Under the cost method of accounting, investments in private companies are carried at cost and are adjusted only for other-than-temporary declines in fair value, distributions of earnings 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, 2005. 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 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.

Sales of product rights for marketable products are recorded as revenue upon disposition of the rights. Included in

**Table of Contents**

other revenue for fiscal 2004 was \$13,910,000, representing income related to the sale of the U.S. and Canadian rights for sertaconazole nitrate 2% cream.

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 year ended March 31, 2005 and 2004. Such allowances were \$349,355,000 and \$264,170,000 at March 31, 2005 and 2004. Other current liabilities include \$51,772,000 and \$28,179,000 at March 31, 2005 and 2004, for certain rebates and other adjustments that are paid to indirect customers.

Three of the Company's customers accounted for 11%, 19% and 16%, respectively, of revenue in fiscal 2005. Two customers accounted for 21% and 15% of revenues in fiscal 2004 and three customers accounted for 16%, 14% and 20%, respectively, of revenues in fiscal 2003.

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

**Advertising Costs.** Advertising costs are expensed as incurred and amounted to \$9,745,000, \$8,997,000 and \$6,381,000 in fiscal years 2005, 2004 and 2003, 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 granted, excluding antidilutive shares, under our stock option plans (see Note 11). At March 31, 2005, 2004 and 2003, there were 6,779,000, 90,000 and 4,854,150 shares, respectively, that were antidilutive.

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

(in thousands, except per share data)

|  |            |            |            |
|--|------------|------------|------------|
| Fiscal year ended March 31,                        | 2005       | 2004       | 2003       |
| Net earnings                                       | \$ 203,592 | \$ 334,609 | \$ 272,353 |
| Weighted average common shares outstanding         | 268,985    | 268,931    | 278,789    |
| Assumed exercise of dilutive stock options         | 4,636      | 7,387      | 3,541      |
| Diluted weighted average common shares outstanding | 273,621    | 276,318    | 282,330    |
| Earnings per common share:                         |            |            |            |
| Basic  | \$ 0.76    | \$ 1.24    | \$ 0.98    |
| Diluted  | \$ 0.74    | \$ 1.21    | \$ 0.96    |

**Stock Options.** In accordance with the provisions of Financial Accounting Standards Board ( FASB ) Statement of Financial Accounting Standards ( 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 the Company had applied the fair value recognition provisions of SFAS No. 123 to stock-based employee compensation:

**Table of Contents***(in thousands, except per share data)*

| Fiscal year ended March 31,  | 2005       | 2004       | 2003       |
|--|------------|------------|------------|
| Net earnings, as reported  | \$ 203,592 | \$ 334,609 | \$ 272,353 |
| Add: Stock-based compensation expense included in reported net earnings, net of related tax effects                          | 3,901      | 2,388      |            |
| Deduct: Total compensation expense determined under fair value based method for all stock awards, net of related tax effects | (16,210)   | (25,261)   | (19,909)   |
| Pro forma net earnings   | \$ 191,283 | \$ 311,736 | \$ 252,444 |
| Earnings per share:  |            |            |            |
| Basic as reported  | \$ 0.76    | \$ 1.24    | \$ 0.98    |
| Basic pro forma  | \$ 0.71    | \$ 1.16    | \$ 0.91    |
| Diluted as reported  | \$ 0.74    | \$ 1.21    | \$ 0.96    |
| Diluted pro forma  | \$ 0.70    | \$ 1.14    | \$ 0.91    |

**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 2005 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 FASB issued SFAS No. 123(R), *Share-Based Payment*. SFAS 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. 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. In April 2005, the SEC delayed the effective date of SFAS 123 (R) to fiscal years beginning after June 15, 2005. Management is currently assessing the impact that adoption of this Statement will have on the Company's Consolidated Financial Statements

**Table of Contents****Note 3. Balance Sheet Components**

Selected balance sheet components consist of the following at March 31, 2005 and 2004:

| <i>(in thousands)</i>                      | 2005       | 2004       |
|--|------------|------------|
| Inventories:                               |            |            |
| Raw materials                              | \$ 119,654 | \$ 149,048 |
| Work in process                            | 39,589     | 34,511     |
| Finished goods                             | 127,024    | 137,238    |
|  | \$ 286,267 | \$ 320,797 |
| Property, plant and equipment:             |            |            |
| Land and improvements                      | \$ 9,704   | \$ 9,704   |
| Buildings and improvements                 | 161,050    | 132,983    |
| Machinery and equipment                    | 269,208    | 240,594    |
| Construction in progress                   | 85,324     | 54,181     |
|  | 525,286    | 437,462    |
| Less accumulated depreciation              | 188,567    | 164,411    |
|  | \$ 336,719 | \$ 273,051 |
| Other current liabilities:                 |            |            |
| Payroll and employee benefit plan accruals | \$ 21,251  | \$ 20,644  |
| Accrued rebates                            | 51,772     | 28,179     |
| Royalties and product license fees         | 11,446     | 20,493     |
| Legal and professional                     | 18,148     | 13,650     |
| Other                                      | 10,989     | 16,688     |
|  | \$ 113,606 | \$ 99,654  |

**Note 4. Marketable Securities**

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

| <i>(in thousands)</i> | Amortized<br>Cost | Gross<br>Unrealized<br>Gains | Gross<br>Unrealized<br>Losses | Fair<br>Value |
|-----------------------|-------------------|------------------------------|-------------------------------|---------------|
| <u>March 31, 2005</u> |                   |                              |                               |               |
| Debt securities       | \$ 669,044        | \$ 194                       | \$ 2,068                      | \$ 667,170    |
| Equity securities     |                   | 3,178                        |                               | 3,178         |
|                       | \$ 669,044        | \$ 3,372                     | \$ 2,068                      | \$ 670,348    |

March 31, 2004

|                   |            |          |        |            |
|-------------------|------------|----------|--------|------------|
| Debt securities   | \$ 580,179 | \$ 1,125 | \$ 92  | \$ 581,212 |
| Equity securities | 1,492      | 2,785    | 44     | 4,233      |
|                   | \$ 581,671 | \$ 3,910 | \$ 136 | \$ 585,445 |

Net unrealized gains on marketable securities are reported net of tax of \$434,000 and \$1,278,000 in fiscal 2005 and fiscal 2004.

Maturities of debt securities at fair value as of March 31, 2005 are as follows:

*(in thousands)*

|                                |            |
|--------------------------------|------------|
| Mature within one year         | \$ 163,175 |
| Mature in one to five years    | 121,919    |
| Mature in five years and later | 382,076    |
|                                | \$ 667,170 |

**Table of Contents**

Gross gains of \$7,000, \$7,322,000 and \$13,650,000 and gross losses of \$67,000, \$813,000 and \$821,000 were realized during fiscal years 2005, 2004 and 2003, respectively.

**Note 5. Intangible Assets**

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

| <i>(in thousands)</i>                                | Weighted<br>Average<br>Life<br>(years) | Original<br>Cost | Accumulated<br>Amortization | Net Book<br>Value |
|--|--|------------------|-----------------------------|-------------------|
| <u>March 31, 2005</u>                                |  |                  |                             |                   |
| Amortized intangible assets:                         |  |                  |                             |                   |
| Patents and technologies                             | 19                                     | \$ 118,935       | \$ 48,478                   | \$ 70,457         |
| Product rights and licenses                          | 12                                     | 111,433          | 69,923                      | 41,510            |
| Other  | 20                                     | 14,267           | 6,524                       | 7,743             |
|  |  | \$ 244,635       | \$ 124,925                  | 119,710           |
| Intangible assets no longer subject to amortization: |  |                  |                             |                   |
| Trademarks   |  |                  |                             | 783               |
|  |  |                  |                             | \$ 120,493        |
| <u>March 31, 2004</u>                                |  |                  |                             |                   |
| Amortized intangible assets:                         |  |                  |                             |                   |
| Patents and technologies                             | 19                                     | \$ 117,435       | \$ 42,304                   | \$ 75,131         |
| Product rights and licenses                          | 12                                     | 109,333          | 59,111                      | 50,222            |
| Other  | 20                                     | 14,267           | 5,802                       | 8,465             |
|  |  | \$ 241,035       | \$ 107,217                  | 133,818           |
| Intangible assets no longer subject to amortization: |  |                  |                             |                   |
| Trademarks   |  |                  |                             | 783               |
|  |  |                  |                             | \$ 134,601        |

Other intangibles consist principally of non-compete agreements, customer lists and contracts.

Amortization expense for fiscal years 2005, 2004 and 2003 was \$17,708,000, \$20,155,000 and \$18,864,000, respectively, and is expected to be \$14,761,000, \$14,483,000, \$14,031,000, \$13,720,000 and \$12,702,000 for fiscal years 2006 through 2010, respectively.

During fiscal 2005, the Company purchased various patents and product licenses in the aggregate amount of \$3,600,000. During fiscal 2004, the Company paid \$4,500,000 for intangible assets acquired as part of a licensing agreement for omeprazole.

**Table of Contents****Note 6. Other Assets**

Other assets consist of the following components at March 31, 2005 and 2004:

| <i>(in thousands)</i>                   | 2005      | 2004      |
|---|-----------|-----------|
| Cash surrender value                    | \$ 38,965 | \$ 35,854 |
| Investments in and advances to Somerset |           | 871       |
| Other                                   | 8,465     | 10,493    |
|   | \$ 47,430 | \$ 47,218 |

Cash surrender value is related to insurance policies on certain officers and key employees and the value of split-dollar life insurance agreements with certain former executive officers.

In November 1988, the Company acquired 50% of the outstanding common stock of Somerset Pharmaceuticals, Inc. ( Somerset ). Mylan accounts for this investment using the equity method of accounting. Equity in loss of Somerset includes our 50% portion of Somerset's financial results, as well as expense for amortization of intangible assets resulting from the acquisition of the interest in Somerset. Such intangible assets are being amortized using the straight-line basis over 15 years. Amortization expense was \$924,000 in each of fiscal years 2005, 2004 and 2003. During fiscal 2004, the Company received a dividend of \$10,000,000 from Somerset. No dividends were received in fiscal years 2005 or 2003. 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 APB No. 18, *The Equity Method of Accounting for Investments in Common Stock*, the Company has temporarily ceased recording losses on this investment.

**Note 7. Revolving Line of Credit**

In July 2004, the Company renewed its agreement with a commercial bank for a revolving line of credit. This line of credit expires on July 31, 2005 and allows Mylan to borrow up to \$50.0 million on an unsecured basis, at an alternative base rate. At the Company's option, it may elect an interest rate based on the published daily London Interbank Offered Rate by giving written notice to the lender. The agreement does not contain any significant financial covenants. At March 31, 2005 and 2004, there were no outstanding borrowings under this line of credit.

**Note 8. Long-Term Obligations**

Long-term obligations consist of the following components at March 31, 2005 and 2004:

| <i>(in thousands)</i>                          | 2005      | 2004      |
|--|-----------|-----------|
| Deferred compensation                          | \$ 17,196 | \$ 17,307 |
| Retirement benefits                            | 3,374     | 2,974     |
| Other  | 341       | 435       |
| Total long-term obligations                    | 20,911    | 20,716    |
| Less: Current portion of long-term obligations | 1,586     | 1,586     |

|   |           |           |
|---|-----------|-----------|
| Long-term obligations, net of current portion | \$ 19,325 | \$ 19,130 |
|---|-----------|-----------|

Deferred compensation consists of the discounted future payments under individually negotiated agreements with certain key employees and directors. The agreements with certain key employees provide for annual payments ranging from \$18,000 to \$1,000,000 to be paid over periods commencing at retirement and ranging from ten years to life.



**Table of Contents****Note 9. Income Taxes**

Income taxes consist of the following components:

| <i>(in thousands)</i>       | 2005       | 2004       | 2003       |
|-----------------------------|------------|------------|------------|
| Fiscal year ended March 31, |            |            |            |
| Federal:                    |            |            |            |
| Current                     | \$ 134,994 | \$ 133,223 | \$ 156,823 |
| Deferred                    | (34,513)   | 30,549     | (18,127)   |
|                             | 100,481    | 163,772    | 138,696    |
| State and Puerto Rico:      |            |            |            |
| Current                     | 10,560     | 12,501     | 17,211     |
| Deferred                    | (2,386)    | 1,726      | (1,747)    |
|                             | 8,174      | 14,227     | 15,464     |
| Income taxes                | \$ 108,655 | \$ 177,999 | \$ 154,160 |
| Pretax earnings             | \$ 312,247 | \$ 512,608 | \$ 426,513 |
| Effective tax rate          | 34.8%      | 34.7%      | 36.1%      |

Temporary differences and carryforwards that result in the deferred tax assets and liabilities are as follows at March 31:

| <i>(in thousands)</i>          | 2005      | 2004     |
|--------------------------------|-----------|----------|
| Deferred tax assets:           |           |          |
| Employee benefits              | \$ 10,301 | \$ 9,824 |
| Contractual agreements         |           |          |
| Intangible assets              | 10,615    | 9,721    |
| Accounts receivable allowances | 113,267   | 75,301   |
| Inventories                    | 3,587     | 1,852    |
| Investments                    | 6,003     | 8,099    |
| Federal tax loss carryforwards |           |          |
| Tax credit carryforwards       |           |          |
| Other                          | 1,117     | 656      |
| Total deferred tax assets      | 144,890   | 105,453  |
| Deferred tax liabilities:      |           |          |
| Plant and equipment            | 22,848    | 19,271   |
| Intangible assets              | 25,946    | 27,915   |
| Investments                    | 1,569     | 2,394    |

|  |            |            |           |
|--|------------|------------|-----------|
| Other  |            | 105        |           |
| Total deferred tax liabilities                     |            | 50,468     | 49,580    |
| Deferred tax asset, net                            |            | \$ 94,422  | \$ 55,873 |
| Classification in the Consolidated Balance Sheets: |            |            |           |
| Deferred income tax benefit                        | current    | \$ 119,327 | \$ 78,477 |
| Deferred income tax liability                      | noncurrent | 24,905     | 22,604    |
| Deferred tax asset, net                            |            | \$ 94,422  | \$ 55,873 |

Deferred tax assets relating to net operating loss carryforwards and research and development tax credit carryforwards were acquired in fiscal 1999 with the acquisition of Penederm. The utilization of these assets is subject to

**Table of Contents**

certain limitations set forth in the U.S. Internal Revenue Code. In fiscal 2003, the Company utilized approximately \$10,709,000 of acquired federal net operating loss carryforwards to reduce its tax liability. In fiscal 2004, the Company utilized the remainder of the net operating loss carryforwards of \$2,707,000 and federal tax credit carryforwards of \$2,092,000.

Federal research and development tax credits of \$567,000 that were deferred at March 31, 2003, due to tax law changes, were applied for and received in fiscal 2004.

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

| Fiscal year ended March 31,        | 2005   | 2004   | 2003   |
|------------------------------------|--------|--------|--------|
| Statutory tax rate                 | 35.0%  | 35.0%  | 35.0%  |
| State and Puerto Rico income taxes | 2.8%   | 2.7%   | 3.3%   |
| State and Puerto Rico tax credits  | (1.3%) | (0.7%) | (0.7%) |
| Federal tax credits                | (2.1%) | (1.8%) | (1.8%) |
| Other items                        | 0.4%   | (0.5%) | 0.3%   |
| Effective tax rate                 | 34.8%  | 34.7%  | 36.1%  |

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

Operations in Puerto Rico benefit from incentive grants from the government of Puerto Rico, which partially exempt the Company from income, property and municipal taxes. In fiscal 2001, a new tax grant was negotiated with the government of Puerto Rico extending tax incentives until fiscal 2010. This grant exempts all earnings during this grant period from tollgate tax upon repatriation of cash to the United States. In fiscal 2004, \$100,000,000 of cash from post-fiscal 2000 earnings was repatriated to the United States. Pursuant to the terms of our new tax grant, no tollgate tax was due for this repatriation.

Under Section 936 of the U.S. Internal Revenue Code, Mylan is a grandfathered entity and is entitled to the benefits under such statute through fiscal 2006. Our Section 936 federal tax credits totaled approximately \$3,874,000 in fiscal 2005 and \$4,732,000 each year in fiscal 2004 and 2003.

Our federal income tax returns have been audited by the Internal Revenue Service through fiscal 2000. We are currently under audit by the Internal Revenue Service for fiscal years 2002 through 2004.

**Note 10. Preferred and Common Stock**

In fiscal 1985, the Board of Directors (the Board) authorized 5,000,000 shares of \$0.50 par value preferred stock. No shares of the preferred stock have been issued.

The Company entered into a Rights Agreement (the Rights Agreement) with American Stock Transfer & Trust Company, as rights agent, in August 1996, and declared a dividend of one share purchase right on each outstanding share of common stock, to provide the Board with sufficient time to assess and evaluate any takeover bid and explore and develop a reasonable response. Effective November 1999, the Rights Agreement was amended to eliminate

certain limitations on the Board's ability to redeem or amend the rights to permit an acquisition and also to eliminate special rights held by incumbent directors unaffiliated with an acquiring shareholder. In August 2004, the Rights Agreement was amended to change the original expiration date of the rights from September 5, 2006 to August 13, 2014. The Rights Agreement was further amended in September 2004, to temporarily change the threshold at which Rights (as defined in the Rights Agreement) will become immediately exercisable from 15% to 10%. By a December 2004 amendment to the Rights Agreement, the term for the lower ownership threshold is set to expire December 31, 2005.

In May 2002, the Board approved a Stock Repurchase Program to purchase up to 22,500,000 shares of our outstanding common stock. This Stock Repurchase Program was administered through open market transactions and purchases of common stock under this program were at market prices. In fiscal 2004, 6,458,700 shares of common stock were purchased for approximately \$133,088,000. The Stock Repurchase Program was completed on November 18, 2003.

**Table of Contents****Note 11. Stock Option Plan**

On July 25, 2003, Mylan's shareholders approved the *Mylan Laboratories Inc. 2003 Long-Term Incentive Plan* (the 2003 Plan). Under the 2003 Plan, 22,500,000 shares of common stock are reserved for issuance to key employees, consultants, independent contractors and non-employee directors of Mylan through a variety of incentive awards including: stock options, stock appreciation rights, restricted shares and units, performance awards, other stock based awards and short-term cash awards. Upon approval of the 2003 Plan, the 1997 Plan was frozen and no further grants of stock options will be made under that plan.

In August 2003, the Company awarded 472,500 shares of restricted common stock to certain executives as permitted under the 2003 Plan. All restricted stock awards entitle the participant to dividend and voting rights. The shares vest at the end of a three-year period. Upon issuance of the restricted shares, unearned compensation of \$11,740,000 was charged to shareholders' equity for the fair value of the restricted stock issued and is being recognized as compensation expense ratably over the three-year period. Compensation expense, net of any related tax effects, for fiscal 2005 and 2004 was \$3,901,000 and \$2,388,000.

Additional stock options are outstanding from the expired plans and other plans assumed through acquisitions.

The following table summarizes stock option activity:

|                               | Number of<br>Shares<br>Under Option | Weighted<br>Average<br>Exercise Price<br>per Share |
|-------------------------------|-------------------------------------|--|
| Outstanding at March 31, 2002 | 19,264,891                          | \$ 10.70   |
| Options granted               | 8,774,028                           | 16.70  |
| Options exercised             | (3,451,660)                         | 15.58  |
| Options forfeited             | (698,778)                           | 12.67  |
| Outstanding at March 31, 2003 | 23,888,481                          | 13.13  |
| Options granted               | 1,911,951                           | 20.08  |
| Options exercised             | (2,667,593)                         | 10.18  |
| Options forfeited             | (302,931)                           | 17.12  |
| Outstanding at March 31, 2004 | 22,829,908                          | 13.99  |
| Options granted               | 649,900                             | 19.05  |
| Options exercised             | (891,092)                           | 11.30  |
| Options forfeited             | (286,928)                           | 19.13  |
| Outstanding at March 31, 2005 | 22,301,788                          | \$ 14.17   |

The following table summarizes information about stock options outstanding as of March 31, 2005:

| Ranges of Exercise | Options Outstanding |         |         | Options Exercisable |         |
|--------------------|---------------------|---------|---------|---------------------|---------|
|                    | Number              | Average | Average | Number              | Average |

Edgar Filing: MYLAN LABORATORIES INC - Form 10-K

| Price per Share   | of Shares  | Life <sup>(1)</sup> | Price <sup>(2)</sup> | of Shares  | Price <sup>(2)</sup> |
|-------------------|------------|---------------------|----------------------|------------|----------------------|
| \$ 6.56 - \$11.27 | 4,547,868  | 5.15                | \$ 10.24             | 4,485,994  | \$ 10.23             |
| 11.34 - 11.58     | 5,587,261  | 5.96                | 11.49                | 5,576,011  | 11.48                |
| 11.62 - 14.82     | 4,500,267  | 6.98                | 13.07                | 4,071,959  | 13.01                |
| 14.99 - 19.36     | 6,288,178  | 7.99                | 18.76                | 2,446,437  | 18.16                |
| 19.43 - 26.00     | 1,378,214  | 8.60                | 20.74                | 203,601    | 21.12                |
| <br>              |            |                     |                      |            |                      |
| \$ 6.56 - \$26.00 | 22,301,788 | 6.74                | \$ 14.17             | 16,784,002 | \$ 12.61             |

---

(1) *Weighted average contractual life remaining in years.*

(2) *Weighted average exercise price per share.*

**Table of Contents**

The number of shares exercisable and the associated weighted average exercise price as of March 31, 2004 was 13,356,216 shares at \$12.03 per share.

SFAS No. 123 requires the calculation of the fair value of options granted during each fiscal year. The fair value of options granted in fiscal years 2005, 2004 and 2003, using the Black-Scholes option pricing model, and the assumptions used are as follows:

| Fiscal year ended March 31,            | 2005    | 2004    | 2003    |
|--|---------|---------|---------|
| Volatility                             | 41.8%   | 41.1%   | 44.0%   |
| Risk-free interest rate                | 3.2%    | 2.7%    | 3.1%    |
| Dividend yield                         | 0.6%    | 0.4%    | 0.5%    |
| Expected term of options (in years)    | 4.2     | 6.5     | 6.0     |
| Weighted average fair value per option | \$ 6.73 | \$ 8.51 | \$ 7.36 |

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

**Note 12. Employee Benefits**

The Company has a plan covering substantially all employees to provide for limited reimbursement of postretirement supplemental medical coverage. In addition, in December 2001, the Supplemental Health Insurance Program for Certain Officers of Mylan Laboratories was adopted to provide full postretirement medical coverage to certain officers and their spouse and dependents. These plans generally provide benefits to employees who meet minimum age and service requirements. The Company accounts for these benefits under SFAS No. 106, *Employers Accounting for Postretirement Benefits Other Than Pensions*. The amounts accrued related to these benefits were not material at March 31, 2005 and 2004.

The Company has defined contribution plans covering essentially all of its employees. Its defined contribution plans consist primarily of a 401(k) retirement plan with a profit sharing component for non-union employees and a 401(k) retirement plan for union employees. Profit sharing contributions are made at the discretion of the Board. The Company's matching contributions are based upon employee contributions or service hours, depending upon the plan. Total employer contributions to all plans for fiscal years 2005, 2004 and 2003 were \$13,382,000, \$11,927,000 and \$11,707,000, respectively.

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

The production and maintenance employees at the Company's manufacturing facilities in Morgantown, West Virginia, are covered under a collective bargaining agreement which expires in April 2007. These employees represented approximately 24% of the Company's total workforce at March 31, 2005.

**Note 13. Segment Reporting**

The Company has two reportable operating segments, a Generic Segment and a Brand Segment, based on differences in products, marketing or regulatory approval. Additionally, certain general and administrative expenses, such as legal expenditures, litigation settlements, and non-operating income and expenses are reported in Corporate/Other.

Generic pharmaceutical products are therapeutically equivalent to a brand name product and are marketed primarily to wholesalers, retail pharmacy chains, mail-order pharmacies and group purchasing organizations. These products are approved for distribution by the FDA through the Abbreviated New Drug Application ( ANDA ) process. Three customers accounted for 20%, 15% and 12%, respectively, of Generic Segment net revenues in fiscal 2005. Two customers accounted for 21% and 11%, respectively, of Generic Segment net revenues in fiscal 2004, while three customers accounted for 20%, 15% and 12% in fiscal 2003.

Brand pharmaceutical products are generally new, patent-protected products marketed directly to health care professionals. These products are approved by the U.S. Food and Drug Administration ( FDA ) primarily through the New Drug Application process. Our Brand Segment also includes off-patent brand products, which have prescriber and customer loyalties and brand recognition, as well as branded



**Table of Contents**

generics which are responsive to promotional efforts. Two customers accounted for 14% and 17% of Brand Segment revenues in fiscal 2005. Three customers accounted for 22%, 27% and 13%, respectively, of Brand Segment revenues in fiscal 2004, while two customers accounted for 13% and 16% in fiscal 2003.

The accounting policies of the operating segments are the same as those described in Note 2. The table below presents segment information for the fiscal years identified. For the Generic and Brand Segments, segment profit represents segment gross profit less direct research and development, selling and marketing, and general and administrative expenses. Generic and Brand Segment assets include property, plant and equipment, trade accounts receivable, inventory and intangible assets other than goodwill, and certain other assets. Corporate/Other assets include consolidated cash, cash equivalents, marketable securities, investment in Somerset and other assets, goodwill and all income tax-related assets.

The following table provides a reconciliation of segment information to total consolidated information:

| <i>(in thousands)</i>                   | 2005         | 2004         | 2003         |
|---|--------------|--------------|--------------|
| Fiscal year ended March 31,             |              |              |              |
| Total revenues                          |              |              |              |
| Generic                                 | \$ 1,012,503 | \$ 1,096,128 | \$ 1,012,617 |
| Brand                                   | 240,871      | 278,489      | 256,575      |
| Consolidated                            | \$ 1,253,374 | \$ 1,374,617 | \$ 1,269,192 |
| Depreciation and amortization expense   |              |              |              |
| Generic                                 | \$ 20,588    | \$ 21,996    | \$ 19,607    |
| Brand                                   | 18,137       | 17,495       | 17,555       |
| Corporate/Other                         | 6,375        | 4,832        | 3,418        |
| Consolidated                            | \$ 45,100    | \$ 44,323    | \$ 40,580    |
| Segment profit (loss)                   |              |              |              |
| Generic                                 | \$ 386,199   | \$ 510,821   | \$ 454,043   |
| Brand                                   | 35,379       | 46,521       | 32,682       |
| Corporate/Other                         | (109,331)    | (44,734)     | (60,212)     |
| Consolidated                            | \$ 312,247   | \$ 512,608   | \$ 426,513   |
| Property, plant and equipment additions |              |              |              |
| Generic                                 | \$ 62,062    | \$ 37,777    | \$ 25,400    |
| Brand                                   | 16,378       | 16,260       | 5,335        |
| Corporate/Other                         | 12,306       | 64,414       | 1,860        |
| Consolidated                            | \$ 90,746    | \$ 118,451   | \$ 32,595    |
| March 31,                               | 2005         | 2004         | 2003         |

Edgar Filing: MYLAN LABORATORIES INC - Form 10-K

|                 |              |              |              |
|-----------------|--------------|--------------|--------------|
| Segment assets  |              |              |              |
| Generic         | \$ 777,648   | \$ 677,450   | \$ 536,171   |
| Brand           | 199,651      | 198,142      | 213,016      |
| Corporate/Other | 1,158,374    | 1,009,469    | 996,036      |
| Consolidated    | \$ 2,135,673 | \$ 1,885,061 | \$ 1,745,223 |

*In fiscal years 2005, 2004 and 2003, segment profit (loss) for Corporate/Other includes a net gain of \$25,990, \$34,758 and \$2,370, respectively, for litigation settlements.*

**Table of Contents**

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

(in thousands)

| Fiscal year ended March 31, | 2005         | 2004         | 2003         |
|-----------------------------|--------------|--------------|--------------|
| Cardiovascular              | \$ 549,378   | \$ 600,238   | \$ 622,911   |
| Central Nervous System      | 337,365      | 330,081      | 335,041      |
| Dermatology                 | 74,048       | 102,513      | 87,369       |
| Gastrointestinal            | 90,987       | 137,743      | 27,356       |
| Other <sup>(1)</sup>        | 201,596      | 204,042      | 196,515      |
|                             | \$ 1,253,374 | \$ 1,374,617 | \$ 1,269,192 |

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

**Note 14. Commitments**

The Company leases certain real property under various operating lease arrangements that expire over the next eight years. These leases generally provide the Company with the option to renew the lease at the end of the lease term. The Company also entered into agreements to lease vehicles, which are typically 24 to 36 months, for use by its sales force and certain key employees. For fiscal years 2005, 2004 and 2003, The Company made lease payments of \$4,939,000, \$3,136,000 and \$5,640,000, respectively.

Future minimum lease payments under these commitments are as follows:

| (in thousands) | Operating<br>Leases |
|----------------|---------------------|
| Fiscal         |                     |
| 2006           | \$ 5,644            |
| 2007           | 4,021               |
| 2008           | 2,748               |
| 2009           | 744                 |
| 2010           | 557                 |
| Thereafter     | 263                 |
|                | \$ 13,977           |

The Company has entered into various product licensing and development agreements. In some of these arrangements, the Company provides funding for the development of the product or to obtain rights to the use of the patent, through milestone payments, in exchange for marketing and distribution rights to the product. Milestones represent the completion of specific contractual events, and it is uncertain if and when these milestones will be achieved. In the event that all projects are successful, milestone and development payments of approximately \$9,300,000 would be paid.

The Company has also entered into employment and other agreements with certain executives that provide for compensation and certain other benefits. These agreements provide for severance payments under certain circumstances. Additionally, the Company has split-dollar life insurance agreements with certain retired executives.

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

## **Table of Contents**

### **Note 15. Related Parties**

Mylan holds an equity interest in a supplier. During fiscal years 2004 and 2003, Mylan paid \$5,651,000 and \$3,715,000, respectively, to the supplier in return for certain raw materials used in production and \$901,000 and \$2,727,000 in fiscal 2004 and 2003, respectively, for royalties under a product licensing agreement with this supplier.

### **Note 16. Contingencies**

#### **Legal Proceedings**

While it is not possible to determine with any degree of certainty the ultimate outcome of the following legal proceedings, the Company believes that it has meritorious defenses with respect to the claims asserted against it and intends to vigorously defend its position. An adverse outcome in any of these proceedings could have a material adverse effect on the Company's financial position and results of operations.

#### *Omeprazole*

In fiscal 2001, Mylan Pharmaceuticals Inc. ( MPI ), a wholly-owned subsidiary of Mylan Laboratories Inc. ( Mylan Labs ), filed an ANDA seeking approval from the Food and Drug Administration ( FDA ) to manufacture, market and sell omeprazole delayed-release capsules, and made Paragraph IV certifications to several patents owned by AstraZeneca PLC ( AstraZeneca ) that were listed in the FDA's Orange Book . On September 8, 2000, AstraZeneca filed suit against MPI and Mylan Labs in the U.S. District Court for the Southern District of New York alleging infringement of several of AstraZeneca's patents. MPI filed multiple motions for summary judgment as to all claims of infringement, and the summary judgment motions remain pending. 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.

In November 2002, MPI filed suit in the U.S. District Court for the District of Delaware against Kremers Urban Development Company ( KUDCo ) and several other companies affiliated with Schwarz Pharma AG (the Schwarz Pharma Group ) alleging KUDCo and the Schwarz Pharma Group are infringing U.S. patent 5,626,875 (the 875 Patent ) in connection with KUDCo's manufacture and sale of omeprazole capsules in the U.S. KUDCo and the Schwarz Pharma Group asserted defenses and counterclaims in that action alleging the inventors listed on the 875 Patent are not the actual inventors of the invention described therein, and further seeking money damages alleging the infringement action was not proper. On August 7, 2003, KUDCo and an individual filed a lawsuit against MPI and Esteve in the U.S. District Court for the District of Columbia asserting claims that were not asserted in the Delaware action. During the first quarter of fiscal 2005, a settlement was agreed to with respect to the cases involving MPI, KUDCo and the Schwarz Pharma Group, and these lawsuits have been dismissed, with prejudice. Under the settlement, MPI received a payment of \$37,500,000, a portion of which represented the reimbursement of legal expenses.

#### *Lorazepam and Clorazepate*

The Company previously reported final court approval in the first quarter of fiscal 2004 of a settlement of a direct purchaser class action related to the sale of lorazepam and clorazepate, which settlement did not include several related cases. Trial on the last remaining case began on May 3, 2005, involving an action brought by a group of health

insurers who opted out of previous class action settlements. These plaintiffs are seeking to recover approximately \$12,000,000 in damages, plus possible trebling and attorneys' fees.

*Pricing and Medicaid Litigation*

On September 26, 2003, the Commonwealth of Massachusetts sued Mylan Labs and 12 other generic drug companies alleging unlawful manipulation of reimbursements under the Massachusetts Medicaid program. The lawsuit identified three drug products sold by MPI, and sought equitable relief, attorneys' fees, cost of litigation and monetary damages in unspecified sums. The court has dismissed the complaint, without prejudice, and granted Massachusetts leave to amend.

**Table of Contents**

On June 26, 2003, UDL and MPI received requests from the U.S. House of Representatives Energy and Commerce Committee requesting information about certain drug products sold by UDL and MPI, in connection with the Committee's investigation into pharmaceutical reimbursement and rebates under Medicaid. UDL and MPI are cooperating with this inquiry and provided information in response to the Committee's requests in 2003. Several states Attorneys General (AGs) have also sent letters to MPI, UDL and Mylan Bertek Pharmaceuticals Inc., a wholly-owned subsidiary of Mylan Labs, 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. Mylan is cooperating with each of these investigations and has begun producing information in response to the subpoenas.

On August 4, 2004, the City of New York filed a civil lawsuit against 44 pharmaceutical companies, including Mylan Labs, in the U.S. District Court for the Southern District of New York alleging violations of federal and state Medicaid laws, Medicaid and common law fraud, breach of contract, other New York statutes and regulations, and unjust enrichment, and on January 26, 2005, the plaintiff filed an amended complaint naming MPI and UDL as defendants. The case has been transferred to the AWP multi-district litigation proceedings pending in the U.S. District Court for the District of Massachusetts for pretrial proceedings. A similar suit was filed by the Commonwealth of Kentucky on November 4, 2004, against Mylan Labs, MPI and approximately 40 other pharmaceutical companies in the Franklin County Circuit Court alleging violations of the Kentucky Consumer Protection Act, the Kentucky Medicaid Fraud Statute, the Kentucky False Advertising Statute, fraud and negligent misrepresentation relating to reporting of average wholesale prices (AWP). In addition, on December 6, 2004, the State of Wisconsin sued Mylan Labs, MPI and approximately 35 other pharmaceutical companies in the Circuit Court for Dane County, Wisconsin alleging violations of Wisconsin false advertising, price reporting and fraud statutes and, the Wisconsin Trusts and Monopolies Act, and also asserting a claim for unjust enrichment. Nassau County, New York filed a similar complaint in the U.S. District Court for the Eastern District of New York on November 24, 2004 containing federal and state claims against numerous pharmaceutical companies including Mylan Labs, MPI and UDL. On January 26, 2005, the Counties of Rockland, Suffolk and Westchester filed amended complaints in the U.S. District Court for the District of Massachusetts against approximately 50 pharmaceutical companies, including Mylan Labs, MPI and UDL, alleging violations of federal and state Medicaid laws, Medicaid and common law fraud, breach of contract, other New York statutes and regulations and unjust enrichment. Onondaga County, New York filed a substantially similar complaint in the U.S. District Court for the Northern District of New York in January 2005. In addition to the case filed by Onandaga County, New York, Mylan Labs, MPI and UDL have been named as defendants along with several dozen other drug manufacturers in lawsuits filed by 22 other counties in the State of New York in March 2005 and April 2005, asserting substantially similar claims to those asserted by Onandaga County. On January 26, 2005, the State of Alabama filed suit against 79 pharmaceutical companies, including Mylan Labs, MPI and UDL, in the Circuit Court of Montgomery County, Alabama, alleging that Alabama has been defrauded by false reporting of AWP, WAC and direct prices and asserts claims for fraud, wantonness and unjust enrichment, seeking compensatory and punitive damages and injunctive relief. In each case, the plaintiff seeks money damages and civil penalties in unspecified amounts and declaratory and injunctive relief, and in each matter Mylan Labs and its subsidiaries have not yet been required to respond to the complaint or the amended complaint, as applicable. The Company intends to defend these actions vigorously.

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.

*Shareholder Litigation*

On November 22, 2004, an individual purporting to be a Mylan Labs shareholder, filed a civil action in the Court of Common Pleas of Allegheny County, Pennsylvania, against Mylan Labs and all members of its Board of Directors alleging that the Board members had breached their fiduciary duties by approving the planned acquisition of King Pharmaceuticals, Inc. ( King ) and by declining to dismantle the Company's anti-takeover defenses to permit an auction of the Company to Carl Icahn or other potential buyers of the Company, and also alleging that certain transactions between the Company and its directors (or their relatives or companies with which they were formerly affiliated) may have been wasteful. On November 23, 2004, a substantially identical complaint was filed in the same court by another purported Mylan Labs shareholder. The actions are styled as shareholder derivative suits on behalf of Mylan Labs and class actions on behalf of all Mylan Labs shareholders, and have been consolidated by the court under the caption In re Mylan Laboratories Inc. Shareholder Litigation. Mylan Labs and its directors filed preliminary objections seeking dismissal of the complaints. On January 19, 2005, the plaintiffs amended their complaints to add Bear Stearns & Co., Inc., Goldman Sachs & Co., Richard



## **Table of Contents**

C. Perry, Perry Corp., American Stock Transfer & Trust Company, and John Does 1-100 as additional defendants, and to add claims regarding trading activity by the additional defendants and the implications on Mylan Labs' shareholder rights agreement. The plaintiffs are seeking injunctive and declaratory relief and undisclosed damages. Mylan Labs and its directors have not yet been required to respond to the amended complaint.

On December 10, 2004, High River Limited Partnership ( High River ), an entity controlled by Carl Icahn, filed suit in the U.S. District Court for the Middle District of Pennsylvania against Mylan Labs, its Vice Chairman and Chief Executive Officer Robert J. Coury, Richard C. Perry, Perry Corp. and John Does 1-100, asserting against the Company a claim for violation of federal securities laws and against the Company and Mr. Coury a claim for alleged breaches of Pennsylvania statutory and common law, in connection with SEC filings and other public statements concerning the planned King acquisition. The complaint also asserts claims under the federal securities laws and Pennsylvania corporate law concerning a possible shareholder vote relating to the proposed merger. On January 27, 2005, the court granted a motion by defendants Perry Corp. and Mr. Perry to transfer the case to the U.S. District Court for the Southern District of New York. Mylan Labs, Mr. Coury and the other defendants have filed motions to dismiss the complaint in its entirety, which motions are currently pending before the court.

On February 22, 2005, High River filed a complaint naming Mylan Labs and its directors in the U.S. District Court for the Middle District of Pennsylvania challenging the validity under Pennsylvania law of amendments to the provisions of the Company's bylaws requiring shareholders to provide advance notice of nominations of directors for election at Mylan Labs' annual meeting of shareholders. Icahn's High River sought a temporary restraining order ( TRO ) in an attempt to block implementation of the advance notice bylaw. The Court denied High River's motion for a TRO, and High River voluntarily withdrew the case without prejudice. On March 24, 2005, High River filed another complaint in the same court naming the same defendants and seeking substantially the same relief. Mylan has moved to dismiss the new action.

### *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.

### *Previously Reported Matters That Have Been Resolved*

#### *Paclitaxel*

In June 2001, Tapestry Pharmaceuticals, Inc. (formerly NAPRO Biotherapeutics Inc.) ( Tapestry ) and Abbott Laboratories Inc. ( Abbott ) filed suit against Mylan Labs, MPI and UDL, also a wholly-owned subsidiary of the Company, in the U.S. District Court for the Western District of Pennsylvania alleging that the manufacture, use and sale of MPI's paclitaxel product, which MPI began selling in July 2001, infringes certain patents owned by Tapestry and allegedly licensed to Abbott. During the first quarter of fiscal 2005, all parties agreed to a settlement of this case and the lawsuit has been dismissed, with prejudice. MPI paid \$9,000,000 pursuant to the settlement.

#### *Mirtazapine*

In fiscal 2004, Mylan Labs and MPI reached an agreement with Organon U.S.A. Inc. ( Organon ) and Akzo Nobel N.V. ( Akzo ) pursuant to which Organon and Akzo agreed to pay MPI \$15,000,000 in settlement of allegations that Organon and Akzo violated antitrust laws by listing U.S. Patent No. 5,977,099 in the FDA's Orange Book, and by suing Mylan and MPI for alleged infringement of that patent. Of the \$15,000,000, which was recorded in the fourth

quarter of fiscal 2004, and collected subsequently, approximately \$4,800,000 represented reimbursement of legal expenses. The underlying patent infringement suit was resolved in favor of Mylan Labs and MPI by summary judgment in December 2002.

*Nifedipine*

In February 2001, Biovail Laboratories Inc. ( Biovail ) filed suit against Mylan Labs, MPI and Pfizer Inc. ( Pfizer ) alleging antitrust violations with respect to agreements entered into between the Company and Pfizer regarding nifedipine. Biovail, Pfizer and the Company agreed to a settlement pursuant to which Biovail dismissed its lawsuit with prejudice. Pfizer, Mylan Labs and MPI were also named as defendants in five other putative class action suits alleging antitrust claims based on the same alleged conduct. The U.S. District Court for the Northern District of West Virginia dismissed three of

**Table of Contents**

the five putative class actions in 2002 and, on March 18, 2004, the court denied the remaining two plaintiffs' motion for class certification. On April 30, 2004, the court dismissed both remaining actions with prejudice.

*Lorazepam and Clorazepate*

On March 31, 2003, the Company announced a tentative settlement of a direct purchaser class action related to the sale of lorazepam and clorazepate for a total amount of \$35,000,000. The Company's co-defendants agreed to an initial contribution of approximately \$7,000,000 toward the \$35,000,000 settlement. The Company's obligation was accrued at March 31, 2003. During the first quarter of fiscal 2004, this settlement received final court approval. Upon receiving such approval, the Company recorded a gain of approximately \$10,000,000 related to additional contributions which the co-defendants agreed in April 2003 to make to the Company. This additional \$10,000,000 reduces the Company's share of the total settlement to approximately \$18,000,000. The Company is to receive the \$10,000,000 in five annual payments of \$2,000,000 each.

*Zagam®*

Mylan Labs, Mylan Caribe, Inc. and Mylan Bertek filed suit against Aventis Pharmaceuticals, Inc., successor in interest to Rhone-Poulenc Rorer Pharmaceuticals, Inc.; Rhone-Poulenc Rorer Pharmaceuticals, LTD; Rorer Pharmaceutical Products, Inc.; Rhone-Poulenc Rorer, S.A., and their affiliates in the U.S. District Court for the Western District of Pennsylvania in May 2001, and the defendants counterclaimed. The Company previously identified this matter as a case in which an adverse outcome could have had a material adverse effect on the Company's financial position and results of operations. In April 2003, the Company entered into a settlement of the matter pursuant to which the Company received a payment of \$12,500,000, the dismissal of the defendants' counterclaims and termination of the agreements in question.

*Buspirone*

In fiscal 2003, the Company reached an agreement in principle with Bristol-Myers Squibb (BMS) which would resolve all disputes between the companies related to buspirone and paclitaxel, BMS' Buspar® and Taxol®, respectively, when finalized. That settlement has become final and the Company has received a one-time payment of approximately \$35,000,000, and non-exclusive, paid-up, royalty free, irrevocable licenses under any applicable BMS patents to manufacture, market and sell buspirone and paclitaxel. The \$35,000,000 is included in litigation settlements, net in the Consolidated Statements of Earnings in fiscal 2003.

**Table of Contents**

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

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

Management evaluated our internal control over financial reporting as of March 31, 2005. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control-Integrated Framework (COSO). As a result of this assessment and based on the criteria in the COSO framework, management has concluded that, as of March 31, 2005, our internal control over financial reporting was effective.

Our independent registered public accounting firm, Deloitte & Touche LLP, has audited management's assessment of our internal control over financial reporting. Deloitte & Touche LLP's opinion on management's assessment and on the effectiveness of our internal control over financial reporting appears on page 61 of this annual report on Form 10-K.

**Table of Contents**

**Report of Independent Registered Public Accounting Firm**

Board of Directors and Shareholders

Mylan Laboratories Inc.:

We have audited the accompanying consolidated balance sheets of Mylan Laboratories Inc. and subsidiaries as of March 31, 2005 and 2004, and the related consolidated statements of earnings, shareholders' equity and cash flows for each of the three years in the period ended March 31, 2005. Our audits also included the financial statement schedule listed in the Index at Item 15. These financial statements and financial statement schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on the financial statements and financial statement schedule based on our audits.

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

In our opinion, such consolidated financial statements present fairly, in all material respects, the financial position of Mylan Laboratories Inc. and subsidiaries as of March 31, 2005 and 2004, and the results of their operations and their cash flows for each of the three years in the period ended March 31, 2005, in conformity with accounting principles generally accepted in the United States of America. Also, in our opinion, such financial statement schedule, when considered in relation to the basic consolidated financial statements taken as a whole, presents fairly in all material respects the information set forth therein.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of the Company's internal control over financial reporting as of March 31, 2005, based on the criteria established in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated May 13, 2005 expressed an unqualified opinion on management's assessment of the effectiveness of the Company's internal control over financial reporting and an unqualified opinion on the effectiveness of the Company's internal control over financial reporting.

Deloitte & Touche LLP  
Pittsburgh, Pennsylvania  
May 13, 2005

**Table of Contents**

**Report of Independent Registered Public Accounting Firm**

Board of Directors and Shareholders

Mylan Laboratories Inc.:

We have audited management's assessment, included in the accompanying Management's Report on Internal Control over Financial Reporting, that Mylan Laboratories Inc. and subsidiaries (the Company) maintained effective internal control over financial reporting as of March 31, 2005, based on criteria established in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express an opinion on management's assessment and an opinion on the effectiveness of the Company's internal control over financial reporting based on our audit.

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

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

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

In our opinion, management's assessment that the Company maintained effective internal control over financial reporting as of March 31, 2005, is fairly stated, in all material respects, based on the criteria established in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of March 31, 2005, based on the criteria established in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated financial statements and financial statement schedule as of and for the year ended March 31,

2005 of the Company and our report dated May 13, 2005 expressed an unqualified opinion on those financial statements and financial statement schedule.

Deloitte & Touche LLP  
Pittsburgh, Pennsylvania  
May 13, 2005

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

(unaudited, in thousands, except per share data)

|                                     | 1st<br>Quarter | 2nd<br>Quarter | 3rd<br>Quarter | 4th<br>Quarter        | Year         |
|-------------------------------------|----------------|----------------|----------------|-----------------------|--------------|
| Fiscal 2005                         |                |                |                |                       |              |
| Total revenues                      | \$ 339,012     | \$ 306,955     | \$ 290,972     | \$ 316,435            | \$ 1,253,374 |
| Gross profit                        | 179,753        | 155,253        | 135,347        | 153,187               | 623,540      |
| Net earnings                        | 82,033         | 48,654         | 34,770         | 38,135                | 203,592      |
| Earnings per share <sup>(1)</sup> : |                |                |                |                       |              |
| Basic                               | \$ 0.31        | \$ 0.18        | \$ 0.13        | \$ 0.14               | \$ 0.76      |
| Diluted                             | \$ 0.30        | \$ 0.18        | \$ 0.13        | \$ 0.14               | \$ 0.74      |
| Share prices <sup>(2)</sup> :       |                |                |                |                       |              |
| High                                | \$ 24.59       | \$ 20.48       | \$ 18.88       | \$ 18.08              | \$ 24.59     |
| Low                                 | \$ 20.15       | \$ 14.69       | \$ 16.42       | \$ 15.88              | \$ 14.69     |
| Fiscal 2004                         |                |                |                |                       |              |
| Total revenues                      | \$ 331,408     | \$ 360,060     | \$ 349,786     | \$ 333,363            | \$ 1,374,617 |
| Gross profit                        | 177,429        | 207,708        | 199,184        | 178,147               | 762,468      |
| Net earnings                        | 83,863         | 91,278         | 84,618         | 74,850 <sup>(3)</sup> | 334,609      |
| Earnings per share <sup>(1)</sup> : |                |                |                |                       |              |
| Basic                               | \$ 0.31        | \$ 0.34        | \$ 0.32        | \$ 0.28               | \$ 1.24      |
| Diluted                             | \$ 0.31        | \$ 0.33        | \$ 0.31        | \$ 0.27               | \$ 1.21      |
| Share prices <sup>(2)</sup> :       |                |                |                |                       |              |
| High                                | \$ 23.57       | \$ 26.85       | \$ 28.16       | \$ 25.82              | \$ 28.16     |
| Low                                 | \$ 17.45       | \$ 20.73       | \$ 22.45       | \$ 22.16              | \$ 17.45     |

(1) The sum of earnings per share for the four quarters may not equal earnings per share for the total year due to changes in the average number of common shares outstanding.

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

(3) Includes \$15.0 million (pre-tax) related to the settlement of certain litigation (See Note 16).

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

None.

**ITEM 9A. Controls and Procedures**



An evaluation was performed under the supervision and with the participation of the Company's management, including the Chief Executive Officer and the Chief Financial Officer, of the effectiveness of the design and operation of the Company's disclosure controls and procedures as of March 31, 2005. Based upon that evaluation, the Chief Executive Officer and the Chief Financial Officer concluded that the Company's disclosure controls and procedures were effective.

No change in the Company's internal control over financial reporting occurred during the last fiscal quarter that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

**Table of Contents**

Management's Report on Internal Control over Financial Reporting is on page 59. Management's assessment of the effectiveness of Mylan's internal control over financial reporting as of March 31, 2005, has been audited by Deloitte & Touche LLP, an independent registered public accounting firm, as stated in their report which is on page 61.

**PART III**

**ITEM 10. Directors and Executive Officers of the Registrant**

*Code of Ethics*

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

The other information required by this Item 10 will be included in an Annual Report on Form 10-K/A to be filed by the Company within 120 days after its fiscal year end (the Form 10-K/A ).

**ITEM 11. Executive Compensation**

The information required by this Item 11 will be included in the Form 10-K/A.

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

The information required by this Item 12 will be included in the Form 10-K/A.

**ITEM 13. Certain Relationships and Related Transactions**

The information required by this Item 13 will be included in the Form 10-K/A.

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

The information required by this Item 14 will be included in the Form 10-K/A.

**PART IV**

**ITEM 15. Exhibits and Financial Statement Schedules**

1. *Consolidated Financial Statements*

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

**Table of Contents**2. *Financial Statement Schedules*

MYLAN LABORATORIES INC.  
 SCHEDULE II - VALUATION AND QUALIFYING ACCOUNTS  
 (in thousands)

| Description                      | Beginning<br>Balance | Additions/Deductions<br>charged to<br>costs and<br>expenses | Deductions | Ending<br>Balance |
|----------------------------------|----------------------|---|------------|-------------------|
| Allowance for Doubtful Accounts: |                      |   |            |                   |
| Fiscal Year Ended                |                      |   |            |                   |
| March 31, 2005                   | \$ 5,965             | \$ 2,007  | \$ 632     | \$ 7,340          |
| March 31, 2004                   | \$ 8,438             | \$ 2,325  | \$ 4,798   | \$ 5,965          |
| March 31, 2003                   | \$ 6,622             | \$ 2,772  | \$ 956     | \$ 8,438          |

3. *Exhibits*

- 3.1 Amended and Restated Articles of Incorporation of the registrant, as amended, filed as Exhibit 3.1 to Form 10-Q for the quarter ended June 30, 2003, and incorporated herein by reference.
- 3.2 Amended and Restated By-laws of the registrant, as amended to date, filed as Exhibit 3.1 to the Report on Form 8-K filed with the SEC on February 22, 2005, and incorporated herein by reference.
- 4.1(a) Rights Agreement dated as of August 22, 1996, between the registrant and American Stock Transfer & Trust Company, filed as Exhibit 4.1 to Form 8-K filed with the SEC on September 3, 1996, and incorporated herein by reference.
- 4.1(b) Amendment to Rights Agreement dated as of November 8, 1999, between the registrant and American Stock Transfer & Trust Company, filed as Exhibit 1 to Form 8-A/A, filed with the SEC on March 31, 2000.
- 4.1(c) Amendment No. 2 to Rights Agreement dated as of August 13, 2004, between the registrant and American Stock Transfer & Trust Company, filed as Exhibit 4.1 to the Report on Form 8-K filed with the SEC on August 16, 2004, and incorporated herein by reference.
- 4.1(d) Amendment No. 3 to Rights Agreement dated as of September 8, 2004, between the registrant and American Stock Transfer & Trust Company, filed as Exhibit 4.1 to the Report on Form 8-K filed with the SEC on September 9, 2004, and incorporated herein by reference.
- 4.1(e) Amendment No. 4 to Rights Agreement dated as of December 2, 2004, between the registrant and American Stock Transfer & Trust Company, filed as Exhibit 4.1 to the Report on Form 8-K filed with the SEC on December 3, 2004, and incorporated herein by reference.

10.1

Edgar Filing: MYLAN LABORATORIES INC - Form 10-K

Mylan Laboratories Inc. 1986 Incentive Stock Option Plan, as amended to date, filed as Exhibit 10(b) to Form 10-K for the fiscal year ended March 31, 1993, and incorporated herein by reference.\*

- 10.2 Mylan Laboratories Inc. 1997 Incentive Stock Option Plan, as amended to date, filed as Exhibit 10.3 to Form 10-Q for the quarter ended September 30, 2002, and incorporated herein by reference.\*

**Table of Contents**

- 10.3 Mylan Laboratories Inc. 1992 Nonemployee Director Stock Option Plan, as amended to date, filed as Exhibit 10(I) to Form 10-K for the fiscal year ended March 31, 1998, and incorporated herein by reference.\*
- 10.4(a) Mylan Laboratories Inc. 2003 Long-Term Incentive Plan, filed as Appendix A to Definitive Proxy Statement on Schedule 14A, filed with the SEC on June 23, 2003, and incorporated herein by reference.\*
- 10.4(b) Form of Stock Option Agreement under the Mylan Laboratories Inc. 2003 Long-Term Incentive Plan\*
- 10.4(c) Form of Restricted Share Award under the Mylan Laboratories Inc. 2003 Long-Term Incentive Plan.\*
- 10.5(a) Executive Employment Agreement dated July 22, 2002, between the registrant and Robert J. Coury, filed as Exhibit 10.1 to Form 10-Q for the quarter ended June 30, 2002, and incorporated herein by reference.\*
- 10.5(b) Amendment No. 1 to Executive Employment Agreement dated as of December 15, 2003, between the registrant and Robert J. Coury, filed as Exhibit 10.15(a) to Form 10-Q for the quarter ended December 31, 2003, and incorporated herein by reference.\*
- 10.6 Executive Employment Agreement dated as of July 1, 2004, between the registrant and Edward J. Borkowski, filed as Exhibit 10.27 to Form 10-Q/A for the quarter ended September 30, 2004 and incorporated herein by reference.\*
- 10.7 Executive Employment Agreement dated as of July 1, 2004, between the registrant and Louis J. DeBone, filed as Exhibit 10.28 to Form 10-Q/A for the quarter ended September 30, 2004 and incorporated herein by reference.\*
- 10.8 Executive Employment Agreement dated as of July 1, 2004, between the registrant and John P. O'Donnell, filed as Exhibit 10.29 to Form 8-K, filed with the SEC on December 3, 2004 and incorporated herein by reference.\*
- 10.9 Executive Employment Agreement dated as of July 1, 2004, between the registrant and Stuart A. Williams, filed as Exhibit 10.30 to Form 10-Q/A for the quarter ended September 30, 2004, and incorporated herein by reference.\*
- 10.10 Form of Employment Agreement dated as of December 15, 2003, between the registrant and certain executive officers (other than named executive officers), filed as Exhibit 10.18 to Form 10-Q for the quarter ended December 31, 2003, and incorporated herein by reference.\*
- 10.11 Retirement Benefit Agreement dated as of December 31, 2004, between the registrant and Robert J. Coury filed as Exhibit 10.7 to Form 10-Q for the quarter ended December 31, 2004, and incorporated herein by reference.\*
- 10.12 Retirement Benefit Agreement dated as of December 31, 2004, between the registrant and Edward J. Borkowski, filed as Exhibit 10.8 to Form 10-Q for the quarter ended December 31, 2004, and incorporated herein by reference.\*
- 10.13 Retirement Benefit Agreement dated as of December 31, 2004, between the registrant and Stuart A. Williams, filed as Exhibit 10.9 to Form 10-Q for the quarter ended December 31, 2004, and incorporated herein by reference.\*

- 10.14 Amended and Restated Retirement Benefit Agreement dated as of December 31, 2004, between the registrant and Louis J. DeBone, filed as Exhibit 10.10 to Form 10-Q for the quarter ended December 31, 2004, and incorporated herein by reference.\*
- 10.15 Amended and Restated Retirement Benefit Agreement dated as of December 31, 2004, between the registrant and John P. O Donnell, filed as Exhibit 10.11 to Form 10-Q for the quarter ended December 31, 2004, and incorporated herein by reference.\*

**Table of Contents**

- 10.16 Retirement Benefit Agreement dated January 27, 1995, between the registrant and C.B. Todd, filed as Exhibit 10(b) to Form 10-K for the fiscal year ended March 31, 1995, and incorporated herein by reference.\*
- 10.17(a) Retirement Benefit Agreement dated January 27, 1995, between the registrant and Milan Puskar, filed as Exhibit 10(b) to Form 10-K for the fiscal year ended March 31, 1995, and incorporated herein by reference.\*
- 10.17(b) First Amendment to Retirement Benefit Agreement dated September 27, 2001, between the registrant and Milan Puskar, filed as Exhibit 10.1 to Form 10-Q for the quarter ended September 30, 2001, and incorporated herein by reference.\*
- 10.18(a) Retirement Benefit Agreement dated March 14, 1995, between the registrant and Patricia Sunseri, filed as Exhibit 10(k) to Form 10-K for the fiscal year ended March 31, 1997, and incorporated herein by reference.\*
- 10.18(b) First Amendment to Retirement Benefit Agreement dated September 27, 2001, between the registrant and Patricia Sunseri, filed as Exhibit 10.1 to Form 10-Q for the quarter ended September 30, 2001, and incorporated herein by reference.\*
- 10.19 Split Dollar Life Insurance Arrangement between the registrant and the Milan Puskar Irrevocable Trust filed as Exhibit 10(h) to Form 10-K for the fiscal year ended March 31, 1996, and incorporated herein by reference.\*
- 10.20 Service Benefit Agreement dated January 27, 1995, between the registrant and Laurence S. DeLynn, filed as Exhibit 10(g) to Form 10-K for fiscal year ended March 31, 1995, and incorporated herein by reference.\*
- 10.21(a) Transition and Succession Agreement dated as of December 15, 2003, between the registrant and Robert J. Coury, filed as Exhibit 10.19 to Form 10-Q for the quarter ended December 31, 2003, and incorporated herein by reference.\*
- 10.21(b) Amendment No. 1 to Transition and Succession Agreement dated as of December 2, 2004, between the registrant and Robert J. Coury, filed as Exhibit 10.1 to Form 10-Q for the quarter ended December 31, 2004, and incorporated herein by reference.\*
- 10.22(a) Transition and Succession Agreement dated as of December 15, 2003, between the registrant and Edward J. Borkowski, filed as Exhibit 10.20 to Form 10-Q for the quarter ended December 31, 2003, and incorporated herein by reference.\*
- 10.22(b) Amendment No. 1 to Transition and Succession Agreement dated as of December 2, 2004, between the registrant and Edward J. Borkowski, filed as Exhibit 10.2 to Form 10-Q for the quarter ended December 31, 2004, and incorporated herein by reference.\*
- 10.23(a) Transition and Succession Agreement dated as of December 15, 2003, between the registrant and Louis J. DeBone, filed as Exhibit 10.21 to Form 10-Q for the quarter ended December 31, 2003, and incorporated herein by reference.\*



- 10.23(b) Amendment No. 1 to Transition and Succession Agreement dated as of December 2, 2004, between the registrant and Louis J. DeBone, filed as Exhibit 10.3 to Form 10-Q for the quarter ended December 31, 2003, and incorporated herein by reference.\*
- 10.24(a) Transition and Succession Agreement dated as of December 15, 2003, between the registrant and John P. O'Donnell, filed as Exhibit 10.22 to Form 10-Q for the quarter ended December 31, 2003, and incorporated herein by reference.\*

**Table of Contents**

- 10.24(b) Amendment No. 1 to Transition and Succession Agreement dated as of December 2, 2004, between the registrant and John P. O'Donnell, filed as Exhibit 10.5 to Form 10-Q for the quarter ended December 31, 2004, and incorporated herein by reference.\*
- 10.25(a) Transition and Succession Agreement dated as of December 15, 2003, between the registrant and Stuart A. Williams, filed as Exhibit 10.23 to Form 10-Q for the quarter ended December 31, 2003, and incorporated herein by reference.\*
- 10.25(b) Amendment No. 1 to Transition and Succession Agreement dated as of December 2, 2004, between the registrant and Stuart A. Williams, filed as Exhibit 10.6 to Form 10-Q for the quarter ended December 31, 2004, and incorporated herein by reference.\*
- 10.26 Amended and Restated Transition and Succession Agreement dated as of November 7, 2001, between the registrant and Patricia Sunseri, filed as Exhibit 10.2 to Form 10-Q for the quarter ended December 31, 2001, and incorporated herein by reference.\*
- 10.27 Form of Transition and Succession Agreement dated as of December 15, 2003, with certain executive officers (other than named executive officers), filed as Exhibit 10.24 to Form 10-Q for the quarter ended December 31, 2003, and incorporated herein by reference.\*
- 10.28 Executives' Retirement Savings Plan, filed as Exhibit 10.14 to Form 10-K for the fiscal year ended March 31, 2001, and incorporated herein by reference.\*
- 10.29 Supplemental Health Insurance Program For Certain Officers of Mylan Laboratories Inc., effective December 15, 2001, filed as Exhibit 10.1 to Form 10-Q for the quarter ended December 31, 2001, and incorporated herein by reference.\*
- 10.30 Mylan Laboratories Inc. Severance Plan, filed as Exhibit 10.12 to Form 10-Q for the quarter ended December 31, 2004, and incorporated herein by reference.\*
- 10.31 Form of Indemnification Agreement between the registrant and each Director, filed as Exhibit 10.31 to Form 10-Q/A for the quarter ended September 30, 2004, and incorporated herein by reference.\*
- 10.32 Description of the registrant's Director Compensation Arrangements in effect as of February 9, 2005, filed as Exhibit 10.13 to Form 10-Q for the quarter ended December 31, 2004, and incorporated herein by reference.\*
- 21 Subsidiaries of the registrant.
- 23 Consent of Independent Registered Public Accounting Firm.
- 31.1 Certification of CEO pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 31.2 Certification of CFO pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 32 Certifications of CEO and CFO pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

---

\* Denotes management contract or compensatory plan or arrangement.



**Table of Contents**

**SIGNATURES**

Pursuant to the requirements of section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this Form to be signed on its behalf by the undersigned, thereunto duly authorized on May 18, 2005.

Mylan Laboratories Inc.

by /s/ ROBERT J. COURY

Robert J. Coury  
Vice Chairman of the Board and Chief Executive  
Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this Form has been signed below by the following persons on behalf of the registrant and in the capacities indicated as of May 18, 2005.

**Signature**

**Title**

/s/ ROBERT J. COURY

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

Robert J. Coury

/s/ EDWARD J. BORKOWSKI

Chief Financial Officer  
*(Principal Financial Officer)*

Edward J. Borkowski

/s/ GARY E. SPHAR

V.P. Corporate Controller  
*(Principal Accounting Officer)*

Gary E. Sphar

/s/ MILAN PUSKAR

Chairman and Director

Milan Puskar

/s/ WENDY CAMERON

Director

Wendy Cameron

/s/ LAURENCE S. DELYNN

Director

Laurence S. DeLynn

/s/ DOUGLAS J. LEECH

Director

Douglas J. Leech

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

Director

Joseph C. Maroon, M.D.

/s/ ROD PIATT

Director

Rod Piatt

/s/ PATRICIA A. SUNSERI

Director

Patricia A. Sunseri

/s/ C.B. TODD

Director

C.B. Todd

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

Director

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

/s/ STUART A. WILLIAMS,  
ESQ.

Director

Stuart A. Williams, Esq.

**Table of Contents**

**EXHIBIT INDEX**

|         |   |
|---------|---|
| 10.4(b) | Form of Stock Option Agreement under the Mylan Laboratories Inc. 2003 Long-Term Incentive Plan. |
| 10.4(c) | Form of Restricted Share Award under the Mylan Laboratories Inc. 2003 Long-Term Incentive Plan. |
| 21      | Subsidiaries of the registrant.   |
| 23      | Consent of Independent Registered Public Accounting Firm.                                       |
| 31.1    | Certification of CEO pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.                 |
| 31.2    | Certification of CFO pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.                 |
| 32      | Certifications of CEO and CFO pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.        |