



**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, 2004

Commission File No. 1-9114

**MYLAN LABORATORIES INC.**

(Exact name of registrant as specified in its charter)

**Pennsylvania**  
(State of Incorporation)

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

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

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

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

<b>Title of Each Class:</b>	<b>Name of Each Exchange on Which Registered:</b>
Common Stock, par value \$0.50 per share	New York Stock Exchange

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

Indicate by check mark 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 voting stock held by non-affiliates of the registrant as of September 30, 2003, the last business day of the Registrant's most recently completed second fiscal quarter, was \$6,733,207,363, based upon the closing price of the common stock on that date, as reported by the New York Stock Exchange. Shares of common stock known to be owned by directors and executive officers of the registrant subject to Section 16 of the Securities Exchange Act of 1934 are not included in the computation. No determination has been made that such persons are "affiliates" within the meaning of Rule 12b-2 under the Exchange Act.

The number of outstanding shares of common stock of the registrant as of June 1, 2004, was 268,555,780.

**DOCUMENTS INCORPORATED BY REFERENCE**

Incorporated by reference into Part III, Items 10-14 of this Form are portions of the registrant's Proxy Statement for the 2004 Annual Meeting of Shareholders, which will be filed with the Securities and Exchange Commission within 120 days after the end of the registrant's fiscal year ended March 31, 2004.

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## 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 2004, the Generic Segment represented approximately 80% of net revenues, and the Brand Segment represented approximately 20% of net revenues. For fiscal 2003 and 2002, the Generic Segment represented approximately 80% and 88% of net revenues, and the Brand Segment represented approximately 20% and 12% of net revenues. The financial information for our operating segments required by this Item is provided in Note 13 to 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

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are developed and manufactured by Mylan Technologies Inc. (“Mylan Tech”), a wholly owned subsidiary of Mylan.

We obtain new 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 lasts for 180 days during which the FDA cannot grant final approval to any other generic equivalent.

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 have bolstered 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 130 in capsule or tablet form in an aggregate of approximately 315 dosage strengths, with 13 extended release products in 27 dosage strengths of which 2 are transdermal patches in 6 dosage strengths. In addition to those products manufactured by Mylan, we are marketing 57 generic products in 102 dosage strengths under supply and distribution agreements with other pharmaceutical companies. At the end of fiscal 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%, 20% and 22% of the Generic Segment’s net revenues in fiscal 2004, 2003 and 2002, respectively, were contributed by calcium channel blockers, primarily nifedipine. In 2002, antianxiety products, primarily buspirone, represented approximately 22% of net revenues.

The future success of our Generic Segment is 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 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, Bertek Pharmaceuticals Inc. (“Bertek”) and Mylan Tech, both of which are wholly owned subsidiaries of 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 a New Drug Application (“NDA”) for the indication of hypertension in April 2004. We believe that we will be able to demonstrate clinically the unique beta 1-receptor blockade selectivity characteristics of this product, which could result in providing certain competitive advantages. 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.

Subsequent to March 31, 2004, Bertek received FDA approval for Apokyn<sup>TM</sup>, (apomorphine hydrochloride injection), as the first and only therapy in the U.S. for the acute, intermittent treatment of hypomobility, “off” episodes associated with advanced Parkinson’s disease. Apokyn, which has orphan drug status, will be available by July 2004.

The Brand Segment sales force consists of approximately 200 sales representatives and managers who promote our products to primary care physicians, dermatologists, neurologists, pharmacists, managed care organizations, governmental agencies and chain drug stores. We expect our sales force to increase as the Brand Segment introduces new products to its product line.

## **Product Development**

Research and development efforts are conducted primarily to enable us to manufacture and market FDA approved pharmaceuticals in accordance with FDA regulations. Research and development expenses were \$100.8 million, \$86.7 million and \$58.8 million in fiscal 2004, 2003 and 2002, 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 unusual factors that affect their bioequivalence or because of unusually stringent regulatory requirements;
- development of drugs that target smaller, specialized or under served 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 FDA Phase IV commitments pertaining to additional preclinical and clinical studies for approved NDA products; and

- 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 or for a new dosage strength or a new delivery system for a drug previously approved under an NDA.

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 record keeping, 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 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 2004, Mylan received 17 application approvals from the FDA, including 10 final ANDA approvals and seven tentative approvals.

As of March 31, 2004, Mylan had 39 original ANDAs and two supplemental ANDAs for new product strengths currently pending FDA approval, which represent products with calendar year 2003 brand sales of approximately \$31 billion. Of these 41 applications, 11 have been granted tentative approval/approvable status and represent approximately \$10 billion in calendar year 2003 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 2005, 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-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 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:



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- 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, 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. Products currently in development and/or pending approval include:

Compound	Indication	Phase	Status
Neurology MT110	Pain management	I	*
Cardiology Nebivolol	Management of Hypertension (high blood pressure)	III	NDA Submitted - 04/30/04

\*To be determined

Additionally, we have pending ANDA submissions and products in development that upon FDA approval may require significant promotional efforts and, therefore, 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. 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. Somerset is currently exploring options with respect to the future marketing of EMSAM.

## **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

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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 65 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 270 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 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 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 and approximately 14%, 15% and 14%, respectively, of net revenues in fiscal 2002.

### **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.

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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 a continuing risk to firms in the pharmaceutical industry. We strive to minimize such risks by adherence to stringent quality control procedures. We maintain insurance to protect against and manage the risks involved in conducting our business. The cost to obtain insurance coverage for such risks has significantly increased due to the environment within the commercial insurance industry resulting in increased deductibles and changes in the levels of coverage. The Company has evaluated and will continue to evaluate the types and levels of insurance coverage purchased. In response to the rising cost of commercial insurance, Mylan began to use a wholly owned insurance subsidiary to insure the first \$10.0 million of its product liability risk. The Company maintains commercial insurance in excess of these limits.

### **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 elect to list, and in some cases have only listed, one supplier in our applications with 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, 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, which is the subject of the application. Upon NDA approval, the FDA lists the approved drug product and these

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patents in the Orange Book. Any applicant who 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 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. For example, the extension of prescription drug coverage to all Medicare recipients has gained significant political support.

### **Seasonality**

Our business is not materially affected by seasonal factors.

### **Environment**

We believe that our operations comply in all material respects with applicable laws and regulations concerning the environment. While it is impossible to predict accurately the future costs associated with environmental compliance and potential remediation activities, compliance with environmental laws is not expected to require significant capital expenditures and has not had, and is not expected to have, a material adverse effect on our earnings or competitive position.

### **Employees**

We employ approximately 2,800 persons, approximately 1,000 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 March 31, 2004, open orders were approximately \$62.3 million as compared to \$50.7 million at March 31, 2003, and \$43.9 million at March 31, 2002. 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. 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. 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 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. 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 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, the FDA cannot grant final approval to any other 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 who filed its ANDA containing such a challenge. Such a situation 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 of our customers 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.**

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 cGMP. Compliance with cGMP regulations requires substantial expenditures of time, money and effort in such areas as production and quality control to ensure full technical compliance. The FDA periodically inspects our manufacturing facilities for compliance. FDA approval to manufacture a drug is site-specific. Failure to comply with cGMP regulations at one of our manufacturing facilities could result in an enforcement action brought by the FDA which could include withholding the approval of NDAs, ANDAs or other product applications of that facility. If the FDA were to require one of our manufacturing facilities to cease or limit production, our business could be adversely affected. Delay and cost in obtaining FDA approval to

manufacture at a different facility also could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

We are subject, as are generally all manufacturers, to various federal, state and local laws regulating working conditions, as well as environmental protection laws and regulations, including those governing the discharge of materials into the environment. Although we have not incurred significant costs associated with complying with environmental provisions in the past, if changes to such environmental laws and regulations are made in the future that require significant changes in our operations or if we engage in the development and manufacturing of new products requiring new or different environmental controls, we may be required to expend significant funds. Such changes could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

**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.**

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”, MAY INCREASE OUR COSTS ASSOCIATED WITH THE INTRODUCTION OR MARKETING OF OUR GENERIC PRODUCTS OR COULD DELAY OR PREVENT SUCH INTRODUCTION. 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:

- 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 trials of brand drugs in pediatric populations as discussed below;
- 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;
- 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;
- seeking to obtain new patents on drugs for which patent protection is about to expire; and
- filing a citizen’s petition with the FDA, which often results in delays of our approvals.

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

Companies that produce brand pharmaceutical products routinely bring litigation against ANDA applicants who 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. Litigation often involves significant expense or can delay or prevent introduction 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 healthcare and legislative healthcare 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 to Medicaid and other recipients. Expansion of these 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 MAY EXPERIENCE UNFAVORABLE OUTCOMES OF SUCH PROCEEDINGS, 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 including, but not limited to, 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 substantial amounts of money or for other relief. If any of these legal proceedings 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 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 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.

**WE MAY MAINTAIN INVESTMENTS IN MARKETABLE DEBT AND/OR EQUITY SECURITIES, OTHER INVESTMENTS, BOTH PUBLICLY AND PRIVATELY HELD, AND MAY MAINTAIN DEPOSIT BALANCES AT FINANCIAL INSTITUTIONS IN EXCESS OF FEDERALLY INSURED AMOUNTS. WE MAY EXPERIENCE DECLINES IN THE MARKET VALUE OF THESE SECURITIES AND/OR LOSSES OF PRINCIPAL INVESTED OR AN UNINSURED LOSS OF DEPOSITED FUNDS. SIGNIFICANT DECLINES OR LOSSES 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.**

To the extent that we maintain investments in marketable debt securities, marketable equity securities, and/or investments in other securities, both publicly and privately held, we are subject to many risks. Such risks include market risk associated with declines in the market values of such securities, interest rate risk and the risk of default. As a result of such risks, we could experience a substantial loss, or may even lose all, of the basis or principal we have invested in such securities. Any such declines or losses could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

**THERE ARE INHERENT UNCERTAINTIES INVOLVED IN ESTIMATES, JUDGMENTS AND ASSUMPTIONS USED IN THE PREPARATION OF FINANCIAL STATEMENTS IN ACCORDANCE WITH GAAP. ANY CHANGES IN ESTIMATES, JUDGMENTS AND ASSUMPTIONS USED COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS, FINANCIAL POSITION AND RESULTS OF OPERATIONS AND COULD CAUSE THE MARKET VALUE OF OUR COMMON STOCK TO DECLINE.**

The consolidated and condensed consolidated financial statements included in the periodic reports we file with the SEC are prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP"). The preparation of financial statements in accordance with GAAP involves making estimates, judgments and assumptions that affect reported amounts of assets (including intangible assets), liabilities, revenues, expenses and income. Estimates, judgments and assumptions are inherently subject to change in the future, and any such changes could result in corresponding changes to the amounts

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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:

Primary Segment	Location	Status	Primary Use
Generic:	North Carolina	Owned	Distribution Warehousing
	West Virginia	Owned	Manufacturing Warehousing Research and Development
		Leased	Administrative Warehousing
	Illinois	Owned	Manufacturing Warehousing Administrative
		Leased	Warehousing Administrative
	Puerto Rico	Owned	Manufacturing Warehousing Administrative
Brand:	North Carolina	Leased	Administrative
	Texas	Owned	Manufacturing Warehousing
	Vermont	Owned	Manufacturing Research and Development Administrative 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.

### **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, MPI filed an ANDA seeking approval from the FDA to manufacture, market and sell omeprazole delayed-release capsules, and made "Paragraph IV" certifications to several patents owned by AstraZeneca PLC ("AstraZeneca") that were listed in the FDA's "Orange Book". AstraZeneca filed suit against MPI and Mylan in the U.S. District Court for the Southern District of New York alleging infringement of several of AstraZeneca's patents. MPI filed a motion for summary judgment as to all claims of infringement, and the summary judgment motion remains 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 announced that MPI had commenced the sale of omeprazole 10 mg and 20 mg delayed-release capsules. AstraZeneca then amended the pending lawsuit to assert claims against Mylan and MPI, and filed a separate lawsuit against MPI's supplier, Esteve Quimica S.A. ("Esteve"), for unspecified money damages and a finding of willful infringement which could result in treble damages, injunctive relief, attorneys' fees, costs of litigation and such further relief as the court deems just and proper.

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. The '875 Patent was issued to Esteve and licensed to MPI. Esteve joined the suit as a co-plaintiff with MPI in December 2002. 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 have not been asserted in the Delaware action. KUDCo and the individual allege that the individual is the sole inventor of the '875 Patent, that the individual owns the '875 Patent and has assigned his ownership interest in the '875 Patent to KUDCo, and that MPI and Esteve are infringing the '875 Patent. The new lawsuit seeks an order directing that the individual be listed as the sole inventor or a co-inventor of the '875 Patent and enjoining MPI from infringing the '875 Patent, together with costs and attorneys' fees.

#### ***Paclitaxel***

In June 2001, NAPRO Biotherapeutics Inc. ("NAPRO") and Abbott Laboratories Inc. ("Abbott") filed suit against Mylan, MPI and UDL in the U.S. District Court for the Western District of Pennsylvania. Plaintiffs allege that the manufacture, use and sale of MPI's paclitaxel product, which MPI began selling in July 2001, infringes certain patents owned by NAPRO and allegedly licensed to Abbott. Plaintiffs seek unspecified damages plus interest, a finding of willful infringement which could result in treble damages, injunctive relief, attorneys' fees, costs of litigation and such equitable and other relief as the court deems just and proper. In December 2003, the district court entered a final judgment

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against Mylan, MPI and UDL, finding that the defendants infringed valid and enforceable patents. The Company has appealed these rulings to the U.S. Court of Appeals for the Federal Circuit. A trial is scheduled for February 2005 to address the plaintiffs' claims for money damages and a finding of willful infringement, which could result in treble damages, attorneys' fees and costs of litigation being assessed against the Company.

Also in December 2003, NAPRO filed a motion for a permanent injunction seeking to prohibit the Company from, among other things, making, using, licensing or selling any paclitaxel product that infringes NAPRO's patents. The district court granted the motion although, recognizing the Company's intention to immediately appeal the ruling, granted a temporary stay of the injunction. The Company filed an emergency motion with the Federal Circuit requesting a stay of the injunction until the appeal is resolved, arguing that equities favored a stay. In February 2004, the Federal Circuit granted the Company's motion.

### ***Pricing and Medicaid Litigation***

Mylan, along with a number of other pharmaceutical manufacturers, was named as a defendant in four lawsuits filed in the state courts of California in which the plaintiffs alleged the defendants unlawfully, unfairly and fraudulently manipulated the reported average wholesale price of various products, allegedly to increase third-party reimbursements to others for their products. All of these lawsuits have been voluntarily dismissed by the plaintiffs.

On September 26, 2003, the Commonwealth of Massachusetts sued Mylan and 12 other generic drug companies alleging unlawful manipulation of reimbursements under the Massachusetts Medicaid program. All defendants have filed a motion to dismiss the case, which remains pending.

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

#### ***Nifedipine***

In February 2001, Biovail Laboratories Inc. ("Biovail") filed suit against Mylan, 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 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 the five putative class actions in 2002 and, on March 18, 2004, the court denied the remaining two plaintiffs' motion for class certification. Mylan and Pfizer agreed to settle both remaining cases in April 2004 and, on April 30, 2004, the court dismissed both remaining actions with prejudice.

#### ***Other Inquiries***

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. Several states' Attorneys General ("AGs") have also sent letters to MPI, UDL and Bertek demanding that those companies retain documents relating to Medicaid reimbursement and rebate calculations pending the outcome of unspecified investigations by those AGs into such matters.

#### ***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.

**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". All share and per share amounts for all periods presented in this Annual Report on Form 10-K have been adjusted to reflect a three-for-two stock split which was effected on October 8, 2003. The following table sets forth the quarterly high and low sales prices for our common stock for the periods indicated:

<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
<b>Fiscal 2003</b>	<b>High</b>	<b>Low</b>
First quarter	\$14.24	\$11.16
Second quarter	15.22	11.60
Third quarter	15.56	12.79
Fourth quarter	19.74	15.56

As of June 2, 2004, there were approximately 167,100 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 Board 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.

**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”, the Consolidated Financial Statements and the 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,	2004	2003	2002	2001	2000
<b>Statements of Earnings:</b>					
Total revenues	\$1,374,617	\$1,269,192	\$1,104,050	\$846,696	\$790,145
Cost of sales	612,149	597,756	480,111	464,521	369,377
Gross profit	762,468	671,436	623,939	382,175	420,768
<b>Operating expenses:</b>					
Research and development	100,813	86,748	58,847	64,385	49,121
Selling and administrative	201,612	173,070	169,913	151,212	148,688
Litigation settlements, net	(34,758)	(2,370)	—	147,000	—
Earnings from operations	494,801	413,988	395,179	19,578	222,959
Equity in loss of Somerset	(7,096)	(4,573)	(4,719)	(1,477)	(4,193)
Other income, net	24,903	17,098	17,863	39,912	23,977
Earnings before income taxes	512,608	426,513	408,323	58,013	242,743
Provision for income taxes	177,999	154,160	148,072	20,885	88,497
Net earnings	\$ 334,609	\$ 272,353	\$ 260,251	\$ 37,128	\$154,246
<b>March 31,</b>	<b>2004</b>	<b>2003</b>	<b>2002</b>	<b>2001</b>	<b>2000</b>
<b>Selected balance sheet data:</b>					
Total assets	\$1,875,290	\$1,745,223	\$1,619,880	\$1,472,500	\$1,343,865
Working capital	1,144,073	962,440	891,598	589,955	600,249
Long-term obligations	19,130	19,943	23,883	25,263	31,903
Total shareholders’ equity	1,659,788	1,446,332	1,402,239	1,132,536	1,203,722
<b>Per common share data:</b>					
<b>Net earnings</b>					
Basic	\$ 1.24	\$ 0.98	\$ 0.92	\$ 0.13	\$ 0.53
Diluted	\$ 1.21	\$ 0.96	\$ 0.91	\$ 0.13	\$ 0.53
Shareholders’ equity - diluted	\$ 6.01	\$ 5.12	\$ 4.89	\$ 3.97	\$ 4.11
Cash dividends declared and paid	\$ 0.10	\$ 0.08	\$ 0.07	\$ 0.07	\$ 0.07
<b>Weighted average common shares outstanding:</b>					
Basic	268,931	278,789	282,432	283,023	290,745
Diluted	276,318	282,330	286,578	285,186	293,004

*In fiscal 2004, we settled various outstanding legal matters for a net gain of \$34,758. In fiscal 2003, we settled various outstanding legal matters for a net gain of \$2,370. 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.*

*All share and per share amounts for all periods presented have been adjusted to reflect a three-for-two stock split which was effected on October 8, 2003.*

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

The following discussion and analysis 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. All share and per share amounts for all periods presented have been adjusted to reflect a three-for-two stock split which was effected on October 8, 2003.

### **Overview**

Mylan Laboratories Inc. and its subsidiaries (“the Company”, “Mylan” or “we”) develop, license, manufacture, market and distribute generic and brand pharmaceutical products. Record revenues, earnings and diluted earnings per share were realized in fiscal 2004, marking the third consecutive year in which such records were achieved. Fiscal 2004 was also the third consecutive year in which revenues exceeded \$1.0 billion, and the second in which that mark was attained by our Generic Segment. Revenues for fiscal 2004 were \$1.37 billion on a consolidated basis and \$1.10 billion for the Generic Segment. Our Brand Segment also realized record revenues in fiscal 2004 of \$278.5 million.

In addition to the record revenues realized during fiscal 2004, each segment’s gross margin improved over the prior year. Fiscal 2004 also saw record net earnings of \$334.6 million and record diluted earnings per share of \$1.21. These achievements were realized while we continued to invest in research and development, which increased 16% or \$14.1 million, and in selling and marketing, as we continue to promote our existing products and prepare for the upcoming launch of new products, including Apokyn<sup>TM</sup>.

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

(in thousands)	FISCAL			CHANGE	
	2004	2003	2002	2004/2003	2003/2002
<b>Consolidated:</b>					
Total revenues	\$1,374,617	\$1,269,192	\$1,104,050	8%	15%
Gross profit	762,468	671,436	623,939	14%	8%
Research and development	100,813	86,748	58,847	16%	47%
Selling and marketing	74,625	65,625	59,913	14%	10%
General and administrative	126,987	107,445	110,000	18%	(2%)
Litigation settlements, net	(34,758)	(2,370)	—	*	—
Earnings from operations	494,801	413,988	395,179	20%	5%
Other income, net	24,903	17,098	17,863	46%	(4%)
Equity in loss of Somerset	(7,096)	(4,573)	(4,719)	(55%)	3%
Pretax earnings	512,608	426,513	408,323	20%	4%
<b>Generic Segment:</b>					
Total revenues	1,096,128	1,012,617	971,075	8%	4%
Gross profit	600,280	531,106	552,736	13%	(4%)
Research and development	59,066	44,562	33,814	33%	32%
Selling and marketing	11,707	11,160	12,430	5%	(10%)
General and administrative	18,686	21,341	23,424	(12%)	(9%)
Earnings from operations	510,821	454,043	483,068	13%	(6%)
<b>Brand Segment:</b>					
Total revenues	278,489	256,575	132,975	9%	93%
Gross profit	162,188	140,330	71,203	16%	97%
Research and development	41,747	42,186	25,033	(1%)	69%
Selling and marketing	62,918	54,465	47,483	16%	15%
General and administrative	11,002	10,997	14,899	0%	(26%)
Earnings (loss) from operations	46,521	32,682	(16,212)	42%	302%
<b>Corporate/Other:</b>					
General and administrative	97,299	75,107	71,677	30%	5%
Litigation settlements, net	(34,758)	(2,370)	—	*	—
Other income, net	24,903	17,098	17,863	46%	(4%)
Equity in loss of Somerset	(7,096)	(4,573)	(4,719)	(55%)	3%

\*Denotes percentage greater than 500%.

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 corporate administrative expenses, such as legal costs, other income and expense, and for fiscal 2002, goodwill amortization. Additionally, in fiscal 2004 and fiscal 2003, Corporate/Other includes net gains of \$34,758 and \$2,370 for litigation settlements.

## Results of Operations

### 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 sale of the U.S. and Canadian rights to sertaconazole nitrate 2% cream 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 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

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Segment's other core products due to royalties paid under a supply and distribution agreement.

### *Research and Development*

Research and development ("R&D") expenses for fiscal 2004 were \$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 expenses 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 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 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. 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.

### *Selling and Marketing*

Selling and marketing expenses for fiscal 2004 were \$74.6 million compared to \$65.6 million in fiscal 2003. As a percentage of revenues, selling and marketing expenses approximated 5% in both years. Generic Segment selling and marketing expenses for fiscal 2004 increased \$0.5 million or 5% to \$11.7 million from \$11.2 million. Brand Segment selling and marketing expenses 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*

General and administrative ("G&A") expenses were \$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 expenses is the result of increased Corporate expenses, partially offset by lower expenses in the Generic Segment.

Generic Segment G&A expenses 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 expenses for fiscal 2004 were \$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

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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.

### *Earnings from Operations*

Consolidated earnings from operations were \$494.8 million or 36% of revenues in fiscal 2004 compared to \$414.0 million or 33% of revenues in fiscal 2003. The Generic Segment generated earnings from operations of \$510.8 million or 47% of revenues in fiscal 2004 compared to \$454.0 million or 45% of revenues in fiscal 2003. For the Brand Segment, earnings from operations in fiscal 2004 were \$46.5 million compared to earnings from operations of \$32.7 million in fiscal 2003. Operating margin for the Brand Segment in fiscal 2004 was 17%. Because of the level of investment in research and development that generally is required to develop branded products, the Brand Segment's operating margin is lower than that of the Generic Segment. Additionally, selling and marketing costs, especially in the year of launch, reduce Brand Segment operating margin.

### *Other Income, Net*

Other income, net of other expenses, was \$24.9 million in fiscal 2004 compared to \$17.1 million in fiscal 2003. This increase of \$7.8 million is primarily the result of a \$5.0 million gain on the sale of an office building and increased earnings from our limited liability partnership investments, partially offset by lower realized gains on the sale of marketable securities. Our limited liability investments yielded income of \$1.8 million in fiscal 2004 compared to a loss of \$2.1 million in fiscal 2003. Fiscal 2003 also included a \$5.7 million impairment charge recorded on an investment which Mylan held in a foreign entity.

### *Equity in Loss of Somerset*

We own a 50% equity interest in Somerset Pharmaceuticals, Inc. ("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.

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 U.S. Food and Drug Administration ("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. Somerset is currently exploring options with respect to the future marketing of EMSAM.

### *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.



## **Fiscal 2003 Compared to Fiscal 2002**

### *Net Revenues and Gross Profit*

Net revenues for fiscal 2003 were \$1.27 billion compared to \$1.10 billion for fiscal 2002, an increase of 15% or \$165.1 million. Both the Generic Segment and the Brand Segment contributed to the overall increase in net revenues. Generic Segment net revenues increased \$41.5 million or 4% over the prior year, while Brand Segment net revenues increased \$123.6 million or 93% over the prior year.

Generic Segment net revenues exceeded \$1.0 billion for the first time in the Company's history, reaching \$1.01 billion compared to \$971.1 million in fiscal 2002. The increase in net revenues is the result of new products launched in fiscal 2003, which contributed net revenues of \$79.5 million, as well as increased volume on existing products. These increases were partially offset by unfavorable pricing as a result of the loss of exclusivity on buspirone in February 2002. Following the entrance into the market of other generic competition, both price and volume erosion are considered normal in the pharmaceutical industry.

Excluding buspirone, Generic Segment net revenues increased \$188.9 million or 24% over the prior year. Generic volume shipped was approximately 11.6 billion doses in fiscal 2003 compared to 10.8 billion doses in fiscal 2002. Our focus is to maximize gross margins within our product portfolio which may result in fluctuations in volume and changes to our product mix.

In fiscal 2003, the Brand Segment generated net revenues of \$256.6 million, an increase of \$123.6 million or 93% over fiscal 2002. Approximately 50% or \$61.2 million of this increase is the result of the launch of Amnesteem in the third quarter of fiscal 2003. Amnesteem was able to achieve a market share of approximately 45% into May of 2003 despite the entrance into the market of other generic competition in March 2003 and April 2003.

In addition to Amnesteem, the increase in Brand Segment net revenues was driven by increased volume and favorable pricing. These increases were the result of continued growth of products in the Company's existing product portfolio, primarily Digitek and phenytoin.

Consolidated gross profit for fiscal 2003 was \$671.4 million, or 53% of net revenues, compared to \$623.9 million, or 57% of net revenues in fiscal 2002. For the Generic Segment, gross profit for fiscal 2003 decreased by \$21.6 million to \$531.1 million from \$552.7 million in fiscal 2002 and decreased as a percentage of net revenues from 57% to 52%. The decrease is primarily due to the loss of exclusivity on buspirone, which resulted in sales of buspirone contributing less to gross profit in fiscal 2003 and at lower gross margins. Margins on the Generic Segment's remaining core products were relatively stable.

Brand Segment gross profit for fiscal 2003 increased by \$69.1 million to \$140.3 million from \$71.2 million in fiscal 2002 and increased as a percentage of net revenues from 54% to 55% on the strength of the Company's existing product portfolio. 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*

Research and development expenses for fiscal 2003 were \$86.7 million or 7% of net revenues compared to \$58.8 million, or 5% of net revenues, in fiscal 2002, which represents an increase of \$27.9 million or 47%. The increase was realized in

both the Generic Segment (increase of \$10.7 million or 32%) and the Brand Segment (increase of \$17.2 million or 69%).

The increase in the Generic Segment was the result of increased studies, an increase in the amount and timing of current and future ANDA submissions and increased research and development headcount. The increase in the Brand Segment was primarily the result of ongoing clinical studies related to nebivolol.

#### *Selling and Marketing*

Selling and marketing expenses for fiscal 2003 were \$65.6 million compared to \$59.9 million in fiscal 2002. As a percentage of revenues, selling and marketing expenses were 5% in both years. Generic Segment selling and marketing expenses for fiscal 2003 decreased \$1.3 million or 10%. Brand Segment selling and marketing expenses increased \$7.0 million or 15% to \$54.5 million in fiscal 2003 from \$47.5 million in fiscal 2002. This increase was the result of increased promotion of existing products, as well as costs associated with the launch of Amnesteem.

#### *General and Administrative*

G&A expenses were \$107.4 million or 8% of net revenues in fiscal 2003, a decrease of \$2.6 million or 2% from fiscal 2002. This decrease is attributed to lower expenses in both the Generic and Brand Segments, partially offset by increased Corporate expenses.

Generic Segment G&A expenses decreased \$2.1 million or 9% to \$21.3 million in fiscal 2003. Brand Segment G&A expenses decreased \$3.9 million or 26% to \$11.0 million in fiscal 2003. The decrease in G&A expenses is primarily the result of the absence of certain costs incurred in the prior year with respect to the write-off of uncollectible accounts and the Brand Segment's relocation of its corporate offices.

Corporate G&A expenses for fiscal 2003 were \$75.1 million compared to \$71.7 million in fiscal 2002. This increase is due primarily to higher legal costs and increased payroll and related costs, partially offset by lower amortization expense as goodwill no longer is amortized as a result of the adoption of Statement of Financial Accounting Standards ("SFAS") No. 142, *Goodwill and Intangible Assets*, on April 1, 2002.

#### *Litigation Settlements*

A net gain of \$2.4 million was recorded in fiscal 2003 with respect to the settlement of various lawsuits. This amount is composed of a \$35.0 million favorable settlement with Bristol-Myers Squibb, which resolved all disputes between the companies related to buspirone and paclitaxel. This was partially offset by a loss of \$27.9 million plus interest related to the settlement of a class action lawsuit filed against the Company concerning the Company's 1998 lorazepam and clorazepate litigation and an unfavorable arbitration decision of \$4.2 million plus interest in connection with a dispute involving verapamil ER.

#### *Earnings from Operations*

Consolidated earnings from operations were \$414.0 million or 33% of net revenues in fiscal 2003 compared to \$395.2 million or 36% of net revenues in fiscal 2002. The Generic Segment generated earnings from operations of \$454.0 million or 45% of net revenues in fiscal 2003 compared to \$483.1 million or 50% of net revenues in fiscal 2002. For the Brand Segment, earnings from operations in fiscal 2003 were \$32.7 million compared to a loss from operations of \$16.2 million in fiscal 2002. Operating margin for the Brand Segment in fiscal 2003 was 13%. Because of the level of investment in research and development and selling and

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marketing that generally is required for branded products, the Brand Segment's operating margin tends to be lower than that of the Generic Segment. Additionally, selling and marketing costs, especially in the year of launch, reduce Brand Segment operating margin.

### *Other Income, Net*

Other income, net of other expenses, was \$17.1 million in fiscal 2003 compared to \$17.9 million in fiscal 2002. This decrease of \$0.8 million is the result of lower earnings from our limited liability partnership investments, which yielded a loss of \$2.1 million in fiscal 2003 compared to net income of \$7.2 million in fiscal 2002 and a \$5.7 million impairment charge recorded on an investment which Mylan holds in a foreign entity, partially offset by net realized gains of \$12.8 million on the sale of marketable securities.

### *Equity in Loss of Somerset*

The recorded loss in Somerset for fiscal 2003 was \$4.6 million compared to a loss of \$4.7 million in fiscal 2002.

### *Income Taxes*

The effective tax rate for fiscal 2003 was 36.1% compared to 36.3% for fiscal 2002. The decrease in the effective tax rate was primarily due to the favorable tax impact of the adoption of SFAS No. 142.

## **Liquidity and Capital Resources**

Cash provided from operations continues to be the primary source of funds to operate and expand our business. Cash flows from operations were \$225.6 million in fiscal 2004. Included in cash flows from operations for fiscal 2004 were net increases in working capital of \$181.6 million to \$1.1 billion from \$962.4 million in fiscal 2003. Inventory represented the most significant increase among working capital items, increasing by \$83.0 million from March 31, 2003. This increase is due to planned production increases in order to meet forecasted demand, as well as recent and planned product launches. We believe that our working capital and cash provided from operating activities are sufficient to meet operating needs. Of the \$1.9 billion in total assets, 37% or \$687.2 million is held in cash, cash equivalents and marketable securities. The table below summarizes cash and cash equivalents and marketable securities at March 31, 2004 and 2003:

	2004	2003
(in thousands)		
Cash and cash equivalents	\$101,713	\$258,902
Marketable securities	585,445	427,904
	<u>\$687,158</u>	<u>\$686,806</u>

Investments in marketable securities are primarily high-quality government and commercial paper. These investments are highly liquid and available for operating needs. Upon maturity, they generally are reinvested in instruments with similar characteristics.

During fiscal 2004, Mylan received payments totaling \$16.0 million related to legal settlements reached during the fiscal year. An additional \$17.0 million was received subsequent to March 31, 2004 with respect to these settlements. During fiscal 2003, Mylan received \$35.0 million as the result of a settlement with Bristol-Myers Squibb resolving all disputes between the companies with respect to buspirone and paclitaxel.

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Additionally during fiscal 2003, two other lawsuits were resolved which resulted in liabilities of \$32.6 million. These liabilities were paid by Mylan during fiscal 2004.

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 Consolidated Financial Statements). As of March 31, 2004, no funds had been advanced under this line of credit. The potential acquisition of new products, as well as businesses, may play a strategic role in our growth. Consequently, such acquisitions may require the use of our cash and marketable securities and additional indebtedness, which would impact future liquidity.

Capital expenditures during fiscal 2004 were \$118.5 million compared to \$32.6 million during fiscal 2003. These expenditures were made primarily as a result of expansions of our manufacturing facilities and to acquire machinery and equipment used in the Company's operations. We expect a similar amount of capital expenditures in fiscal 2005 as these planned expansions continue.

In fiscal 2004, the Board of Directors (the "Board") voted to increase the quarterly dividend by 35% to 3.0 cents per share. Dividend payments totaled \$26.0 million during fiscal 2004 and \$21.2 million during fiscal 2003. In fiscal 2004, we received \$26.7 million from the exercise of stock options issued through our stock option plans compared to \$30.4 million in fiscal 2003.

In May 2002, the Board approved a Stock Repurchase Program that authorized the purchase of up to 22.5 million shares of our outstanding common stock. In fiscal 2004, 6.5 million shares of common stock were purchased for \$133.1 million. In fiscal 2003, 16.0 million shares of common stock were purchased for \$240.5 million. This program was completed on November 18, 2003.

### *Contractual Obligations*

The following table summarizes our contractual obligations at March 31, 2004 and the effect that such obligations are expected to have on our liquidity and cash flows in future periods.

As of March 31, 2004	Total	Less than One Year	One - Three Years	Three - Five Years	Thereafter
(in thousands)					
Operating leases	\$12,606	\$4,922	\$ 7,128	\$ 169	\$ 387
Long-term obligations	19,130	2,220	6,660	6,660	3,590
Line of credit	—	—	—	—	—
Letters of credit	775	775	—	—	—
	<u>\$32,511</u>	<u>\$7,917</u>	<u>\$13,788</u>	<u>\$6,829</u>	<u>\$3,977</u>

We lease certain real property under various operating lease arrangements that expire over the next eight years. These leases generally provide us with the option to renew the lease at the end of the lease term. We have also entered into agreements to lease vehicles, which are typically 24 to 36 months, for use by our 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.

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We maintain a revolving line of credit with a commercial bank. This line of credit expires on July 31, 2004 and allows Mylan to borrow up to \$50.0 million on an unsecured basis, at an interest rate based on the published daily London Interbank Offered Rate. At the Company's option, it may elect an alternative base rate as the interest rate by giving written notice to the lender. The agreement does not contain any significant financial covenants. At March 31, 2004 and 2003, 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 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 \$8.5 million would be paid over the next five years.

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.

The Company is involved in various legal proceedings (see Note 16 to 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 our cash flows.

### **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; the determination of impairment of goodwill and intangibles; 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 \$264.2 million and \$283.0 million at March 31, 2004 and 2003, respectively. Other current liabilities include \$27.9 million and \$33.1 million at March 31, 2004 and 2003, respectively, for certain rebates and other adjustments that are paid to indirect customers. The decrease in sales allowances included in accounts receivable is primarily the result of lower chargebacks accrued at March 31, 2004 compared to March 31, 2003. The accrual for chargebacks decreased by \$18.7 million primarily as a result of a higher concentration of sales of products, including new products, with lower chargeback rates in fiscal 2004 compared to fiscal 2003. Also, a higher percentage of fiscal 2004 sales were made to customers to whom chargebacks are not applicable. See below for further discussion of chargebacks. Provisions for estimated discounts, rebates, promotional and other credits require a lower degree of subjectivity and are less complex in nature; yet combined, they 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. 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. 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.

*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. We continually monitor our provision for chargebacks and make adjustments when we believe that actual chargebacks may differ from established reserves.

### *Impairment of Goodwill and Intangible Assets*

The Company has recorded on its balance sheet both goodwill and intangible assets, which consist of patents and technologies, product rights, brand names and trademarks. Historically, goodwill and intangible assets were reviewed for impairment when events or other changes in circumstances had indicated that the carrying amount of the assets may not be recoverable. In conjunction with the adoption of the Financial Accounting Standards Board (“FASB”) SFAS No. 142, in fiscal 2003, the Company tested all goodwill and intangible assets for impairment. These tests were performed again during fiscal 2004 in accordance with SFAS No. 142.

Impairment of goodwill and indefinite-lived intangibles is determined to exist when the fair value is less than the carrying value of the assets being tested. Impairment of definite-lived intangibles is determined to exist when undiscounted cash flows related to the assets are less than the carrying value of the assets. In assessing impairment, valuations were prepared with the assistance of third parties. Because this process involved management making estimates with respect to future sales volumes, pricing, new product launches, anticipated cost environment and overall market conditions and because these estimates formed the basis for the determination of whether or not an impairment charge should be recorded, these estimates were considered to be critical accounting estimates. As of March 31, 2004, the Company determined through its estimates that no impairment of goodwill or intangible assets existed. The Company will continue to assess the carrying value of its goodwill and intangible assets in accordance with applicable accounting guidance.

### *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, 2004 that for each of the various legal proceedings in which we are involved, the conditions mentioned above were not met. As such, no accrual was recorded. The Company will continue to evaluate all legal matters as additional information becomes available.

### **Recent Accounting Pronouncements**

In January 2003, the FASB issued Interpretation No. 46, *Consolidation of Variable Interest Entities* (“FIN 46”). FIN 46, as revised by the FASB in December 2003, provides guidance with respect to the consolidation of certain entities, referred to as variable interest entities (“VIE”), in which an investor is subject to a majority of the risk of loss from the VIE’s activities, or is entitled to receive a majority of the VIE’s residual returns. This interpretation also provides guidance with respect to the disclosure of VIEs in which an investor maintains an interest, but is not required to consolidate. The provisions of FIN 46 are effective March 31, 2004. The Company has completed its assessment and the adoption of FIN 46 did not have a material impact on the Company’s financial position or results of operations.

### **Forward-Looking Statements**

The statements set forth in this Annual Report on Form 10-K concerning the manner in which we intend to conduct our future operations, potential trends that may impact

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future results of operations and our beliefs or expectations about future operations are forward-looking statements. The following statements that we make in this Annual Report on Form 10-K are or may constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and are made pursuant to the safe harbor provisions of such Act:

- (i) any statement regarding possible or assumed future results of operations of our business, the markets for our products, anticipated expenditures, regulatory developments or competition;
- (ii) any statement preceded by, followed by or that includes the words “intends,” “estimates,” “believes,” “expects,” “anticipates,” “should,” “could,” or the negative or other variations of these or other similar expressions; and
- (iii) other statements regarding matters that are not historical facts.

Because such statements inherently involve risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those described herein under the caption “Risk Factors” in Item I.

**Readers are urged to carefully review and consider those risk factors. We undertake no duty to update the forward-looking statements even though our situation may change in the future.**

### **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, 2004 and 2003:

(in thousands)	2004	2003
Marketable debt securities	\$581,212	\$419,135
Marketable equity securities	4,233	8,769
	<u>\$585,445</u>	<u>\$427,904</u>

#### *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 \$581.2 million invested in marketable debt securities at March 31, 2004, \$78.5 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 \$502.7 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 \$25.1 million change in marketable debt securities.



*Marketable Equity Securities*

Marketable equity securities are primarily managed by professional portfolio managers whose investment objective is to increase fund value through purchasing undervalued common stocks and holding these securities for a period of time. These portfolio managers are continually evaluating the portfolio to ensure that it meets our investment objectives. As of March 31, 2004, a 10% change in the market value of these investments would result in a \$0.4 million change in marketable equity securities.

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

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Supplementary Financial Information**

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

March 31,	2004	2003
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 101,713	\$ 258,902
Marketable securities	585,445	427,904
Accounts receivable, net	191,094	187,587
Inventories	320,797	237,777
Deferred income tax benefit	78,477	104,173
Prepaid expenses and other current assets	40,315	11,868
Total current assets	1,317,841	1,228,211
Property, plant and equipment, net	273,051	178,330
Intangible assets, net	134,601	150,256
Goodwill	102,579	102,581
Other assets	47,218	85,845
Total assets	<u>\$1,875,290</u>	<u>\$1,745,223</u>
<b>Liabilities and shareholders' equity</b>		
Liabilities		
Current liabilities:		
Trade accounts payable	\$ 40,639	\$ 66,017
Income taxes payable	23,837	50,600
Current portion of long-term obligations	1,586	1,586
Cash dividends payable	8,052	6,031
Litigation settlements	—	32,630
Other current liabilities	99,654	108,907
Total current liabilities	173,768	265,771
Long-term obligations	19,130	19,943
Deferred income tax liability	22,604	13,177
Total liabilities	<u>215,502</u>	<u>298,891</u>
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 2004 and 300,000,000 in 2003		
Shares issued: 303,553,121 in 2004 and 300,904,262 in 2003	151,777	150,452
Additional paid-in capital	338,143	304,350
Retained earnings	1,637,497	1,330,933
Accumulated other comprehensive earnings	2,496	3,718
	2,129,913	1,789,453
Less treasury stock - at cost		
Shares: 35,129,643 in 2004 and 29,143,443 in 2003	470,125	343,121
Total shareholders' equity	1,659,788	1,446,332
Total liabilities and shareholders' equity	<u>\$1,875,290</u>	<u>\$1,745,223</u>

*See Notes to Consolidated Financial Statements.*

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

Fiscal year ended March 31,	2004	2003	2002
Revenues:			
Net revenues	\$1,360,707	\$1,269,192	\$1,104,050
Other revenue	13,910	—	—
Total revenues	1,374,617	1,269,192	1,104,050
Cost of sales	612,149	597,756	480,111
Gross profit	762,468	671,436	623,939
Operating expenses:			
Research and development	100,813	86,748	58,847
Selling and marketing	74,625	65,625	59,913
General and administrative	126,987	107,445	110,000
Litigation settlements, net	(34,758)	(2,370)	—
Earnings from operations	494,801	413,988	395,179
Equity in loss of Somerset	(7,096)	(4,573)	(4,719)
Other income, net	24,903	17,098	17,863
Earnings before income taxes	512,608	426,513	408,323
Provision for income taxes	177,999	154,160	148,072
Net earnings	\$ 334,609	\$ 272,353	\$ 260,251
Earnings per common share:			
Basic	\$ 1.24	\$ 0.98	\$ 0.92
Diluted	\$ 1.21	\$ 0.96	\$ 0.91
Weighted average common shares outstanding:			
Basic	268,931	278,789	282,432
Diluted	276,318	282,330	286,578

*See Notes to Consolidated Financial Statements.*

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

Fiscal year ended March 31,	2004	2003	2002
Common stock - - shares issued:			
Shares at beginning of year	300,904,262	297,451,189	294,051,965
Fractional shares issued relative to the stock split	—	1,413	—
Stock options exercised	2,648,859	3,451,660	3,399,224
Shares at end of year	<u>303,553,121</u>	<u>300,904,262</u>	<u>297,451,189</u>
Treasury stock:			
Shares at beginning of year	(29,143,443)	(13,079,325)	(12,896,805)
Shares acquired upon the exercise of stock options	—	(22,818)	(182,520)
Issuance of restricted stock	472,500	—	—
Stock purchases	(6,458,700)	(16,041,300)	—
Shares at end of year	<u>(35,129,643)</u>	<u>(29,143,443)</u>	<u>(13,079,325)</u>
Common shares outstanding	<u>268,423,478</u>	<u>271,760,819</u>	<u>284,371,864</u>
Common stock, \$0.50 par:			
Balance at beginning of year	\$ 150,452	\$ 148,725	\$ 147,025
Stock options exercised	1,325	1,727	1,700
Balance at end of year	<u>151,777</u>	<u>150,452</u>	<u>148,725</u>
Additional paid-in capital:			
Balance at beginning of year	304,350	267,094	241,307
Fractional shares issued relative to the stock split	—	49	—
Stock options exercised	25,342	29,035	22,078
Issuance of restricted stock	5,656	—	—
Unearned compensation	(9,352)	—	—
Tax benefit of stock option plans	12,159	8,172	3,709
Other	(12)	—	—
Balance at end of year	<u>338,143</u>	<u>304,350</u>	<u>267,094</u>
Retained earnings:			
Balance at beginning of year	1,330,933	1,080,736	840,741
Net earnings	334,609	272,353	260,251
Dividends declared (\$0.10 per share for fiscal 2004, \$0.08 per share for fiscal 2003 and \$0.07 per share for fiscal 2002)	(28,045)	(22,156)	(20,256)
Balance at end of year	<u>1,637,497</u>	<u>1,330,933</u>	<u>1,080,736</u>
Accumulated other comprehensive earnings:			
Balance at beginning of year	3,718	7,920	2,983
Net unrealized (loss) gain on marketable securities	(1,222)	(4,202)	4,937
Balance at end of year	<u>2,496</u>	<u>3,718</u>	<u>7,920</u>
Treasury stock, at cost:			
Balance at beginning of year	(343,121)	(102,236)	(99,520)
Shares acquired upon the exercise of stock options	—	(344)	(2,716)
Issuance of restricted stock	6,084	—	—
Stock purchases	(133,088)	(240,541)	—
Balance at end of year	<u>(470,125)</u>	<u>(343,121)</u>	<u>(102,236)</u>
Total shareholders' equity	<u>\$ 1,659,788</u>	<u>\$ 1,446,332</u>	<u>\$ 1,402,239</u>
Comprehensive earnings:			
Net earnings	\$ 334,609	\$ 272,353	\$ 260,251
Other comprehensive (loss) earnings, net of tax:			
Net unrealized holding gains on securities	3,009	4,140	5,195
Reclassification for gains included in net earnings	(4,231)	(8,342)	(258)
Other comprehensive (loss) earnings, net of tax	<u>(1,222)</u>	<u>(4,202)</u>	<u>4,937</u>
Comprehensive earnings	<u>\$ 333,387</u>	<u>\$ 268,151</u>	<u>\$ 265,188</u>

*See Notes to Consolidated Financial Statements.*

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

Fiscal year ended March 31,	2004	2003	2002
Cash flows from operating activities:			
Net earnings	\$ 334,609	\$ 272,353	\$ 260,251
Adjustments to reconcile net earnings to net cash provided from operating activities:			
Depreciation and amortization	44,323	40,580	46,111
Realized gain on sale of marketable securities	(6,509)	(12,829)	(398)
Net loss (earnings) from equity method investees	4,459	5,846	(2,212)
Change in estimated sales allowances	(24,016)	79,895	95,728
Deferred income tax expense (benefit)	32,275	(22,025)	(36,021)
Write-down of investments and intangible assets	—	7,571	2,982
Gain on sale of building	(5,000)	—	—
Other non-cash items	765	3,214	1,162
Litigation settlements, net	(34,758)	(2,370)	—
Receipts from litigation settlements	16,000	35,000	—
Payments of litigation settlements	(32,630)	(4,014)	(7,986)
Cash received from Somerset	10,000	—	—
Changes in operating assets and liabilities:			
Accounts receivable	18,617	(113,155)	4,563
Inventories	(83,020)	(42,558)	(30,696)
Trade accounts payable	(25,378)	29,183	(12,394)
Income taxes	(11,096)	4,801	30,553
Other operating assets and liabilities, net	(13,063)	31,651	(5,172)
Net cash provided from operating activities	<u>225,578</u>	<u>313,143</u>	<u>346,471</u>
Cash flows from investing activities:			
Proceeds from (purchase of):			
Capital assets	(118,451)	(32,595)	(20,621)
Reduction of investment in a limited liability partnership	7,269	1,359	9,535
Sale of assets	12,000	30	4,848
Marketable securities	(793,539)	(821,902)	(819,038)
Sale of marketable securities	640,511	871,904	426,045
Other items, net	1,884	(2,528)	(8,195)
Net cash (used in) provided from investing activities	<u>(250,326)</u>	<u>16,268</u>	<u>(407,426)</u>
Cash flows from financing activities:			
Payments on long-term obligations	—	—	(8,095)
Cash dividends paid	(26,024)	(21,192)	(20,195)
Purchase of common stock	(133,088)	(240,541)	—
Proceeds from exercise of stock options	26,671	30,434	20,852
Net cash used in financing activities	<u>(132,441)</u>	<u>(231,299)</u>	<u>(7,438)</u>
Net (decrease) increase in cash and cash equivalents	(157,189)	98,112	(68,393)
Cash and cash equivalents - beginning of year	258,902	160,790	229,183
Cash and cash equivalents - end of year	<u>\$ 101,713</u>	<u>\$ 258,902</u>	<u>\$ 160,790</u>
Supplemental disclosures of cash flow information:			
Cash paid during the year for:			
Interest	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 238</u>
Income taxes	<u>\$ 156,821</u>	<u>\$ 171,382</u>	<u>\$ 152,145</u>
Non-cash investing activities:			
Marketable securities received from liquidation of investment in limited liability partnership	<u>\$ —</u>	<u>\$ 16,445</u>	<u>\$ —</u>
Non-cash financing activities:			
Issuance of restricted stock	<u>\$ 11,740</u>	<u>\$ —</u>	<u>\$ —</u>

*See Notes to Consolidated Financial Statements.*

**Mylan Laboratories Inc.**

**Notes to Consolidated Financial Statements**

**Note 1. Nature of Operations**

Mylan Laboratories Inc. and its subsidiaries (“the Company”, “Mylan”, or “we”) 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.

**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 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.

We invest our excess cash in high-quality, liquid money market instruments (principally commercial paper, government, municipal and government agency notes and bills) maintained by financial institutions. We maintain deposit balances at certain of these financial institutions in excess of federally insured amounts.

We perform ongoing credit evaluations of our customers and generally do not require collateral. Approximately 58% and 61% of the accounts receivable balances represent amounts due from four customers at March 31, 2004 and 2003, respectively. Total allowances for doubtful accounts were \$5,965,000 and \$8,438,000 at March 31, 2004 and 2003, respectively.

**Inventories.** Inventories are stated at the lower of cost or market, with cost determined by the first-in, first-out method. Provisions for potentially obsolete or slow-moving inventory 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). We periodically review the original estimated useful lives of assets and make adjustments when appropriate. Depreciation expense was \$23,237,000, \$20,780,000 and \$19,729,000 for fiscal years 2004, 2003 and 2002, 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. We periodically review the original estimated useful lives of assets and make 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 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 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. Other-than-temporary declines in fair value are identified by evaluating market conditions and the entity's ability to achieve forecast and regulatory submission guidelines, as well as the entity's overall financial condition.

**Revenue Recognition.** We recognize revenue for product sales upon shipment when title and risk of loss pass to our 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, 2004. The following briefly describes the nature of each provision and how such provisions are estimated.

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

Rebates are offered to our 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. We are 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, 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.

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 which our customer has remaining in its inventory 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.

We have 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 of our 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 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, which were \$264,170,000 and \$283,013,000 at March 31, 2004 and 2003, respectively. Other current liabilities include \$27,924,000 and \$33,096,000 at March 31, 2004 and 2003, respectively, for certain rebates and other adjustments that are paid to indirect customers.

Two of our customers accounted for 21% and 15%, respectively, of revenues in fiscal 2004. Three of our customers accounted for 16%, 14% and 20%, respectively, of revenues in fiscal 2003, and 14%, 15% and 14%, respectively, of revenues in fiscal 2002.

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

**Advertising Costs.** Advertising costs are expensed as incurred and amounted to \$8,997,000, \$6,381,000 and \$7,315,000 in fiscal years 2004, 2003 and 2002, 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.

**Stock Split.** On October 8, 2003, the Company effected a three-for-two split of its common stock. All share and per share amounts contained in the Consolidated Financial Statements, and in these notes, have been adjusted for all periods to reflect the stock split.

**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, 2004, 2003 and 2002, there were 90,000, 4,854,150 and 292,500 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,	2004	2003	2002
Net earnings	\$334,609	\$272,353	\$260,251
Weighted average common shares outstanding	268,931	278,789	282,432
Assumed exercise of dilutive stock options	7,387	3,541	4,146
Diluted weighted average common shares outstanding	276,318	282,330	286,578
Earnings per common share:			
Basic	\$ 1.24	\$ 0.98	\$ 0.92
Diluted	\$ 1.21	\$ 0.96	\$ 0.91

**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*, we account for our stock option plans under the intrinsic-value-based method as defined in Accounting Principles Board 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:

(in thousands, except per share data) Fiscal year ended March 31,		2004	2003	2002
Net earnings, as reported		\$334,609	\$272,353	\$260,251
Add:	Stock-based compensation expense included in reported net earnings, net of related tax effects	2,388	—	—
Deduct:	Total compensation expense determined under fair value based method for all stock awards, net of related tax effects	(25,261)	(19,909)	(20,284)
Pro forma net earnings		\$311,736	\$252,444	\$239,967
Earnings per share:				
Basic - as reported		\$ 1.24	\$ 0.98	\$ 0.92
Basic - pro forma		\$ 1.16	\$ 0.91	\$ 0.85
Diluted - as reported		\$ 1.21	\$ 0.96	\$ 0.91
Diluted - pro forma		\$ 1.14	\$ 0.91	\$ 0.84

**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 2004 presentation.

**Fiscal Year.** Our fiscal year ends on March 31. All references to fiscal year shall mean the 12 months ended March 31.

**Recent Accounting Pronouncements.** Effective April 1, 2002, the Company adopted the provisions of SFAS No. 142, *Goodwill and Other Intangible Assets*. Goodwill and other indefinite lived intangible assets are no longer amortized. Assuming the adoption of SFAS No. 142 had occurred on April 1, 2001, and goodwill and other indefinite-lived assets were no longer amortized, net earnings for fiscal 2002 would have increased by \$7,204,000 and earnings per basic and diluted share would have increased by \$0.03 per share and \$0.02 per share, respectively.

In January 2003, the FASB issued Interpretation No. 46, *Consolidation of Variable Interest Entities* ("FIN 46"). FIN 46, as revised by the FASB in December 2003, provides guidance with respect to the consolidation of certain entities, referred to as variable interest entities ("VIE"), in which an investor is subject to a majority of the risk of loss from the VIE's activities, or is entitled to receive a majority of the VIE's residual returns. This interpretation also provides guidance with respect to the disclosure of VIEs in which an investor maintains an interest, but is not required to consolidate. The provisions of FIN 46 are effective March 31, 2004. The Company has completed its assessment and the adoption of FIN 46 did not have a material impact on the Company's financial position or results of operations.

### Note 3. Balance Sheet Components

Selected balance sheet components consist of the following at March 31, 2004 and 2003:

(in thousands)	2004	2003
<b>Inventories:</b>		
Raw materials	\$149,048	\$107,731
Work in process	34,511	33,990
Finished goods	137,238	96,056
	<u>\$320,797</u>	<u>\$237,777</u>
<b>Property, plant and equipment:</b>		
Land and improvements	\$ 9,704	\$ 9,089
Buildings and improvements	132,983	108,156
Machinery and equipment	240,594	195,300
Construction in progress	54,181	20,346
	<u>437,462</u>	<u>332,891</u>
Less accumulated depreciation	<u>164,411</u>	<u>154,561</u>
	<u>\$273,051</u>	<u>\$178,330</u>
<b>Other current liabilities:</b>		
Payroll and employee benefit plan accruals	\$ 20,644	\$ 18,371
Accrued rebates	27,924	33,096
Royalties and product license fees	20,493	34,465
Other	30,593	22,975
	<u>\$ 99,654</u>	<u>\$108,907</u>

### Note 4. Marketable Securities

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

(in thousands)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
<b>March 31, 2004</b>				
Debt securities	\$580,179	\$1,125	\$ 92	\$581,212
Equity securities	1,492	2,785	44	4,233
	<u>\$581,671</u>	<u>\$3,910</u>	<u>\$136</u>	<u>\$585,445</u>
<b>March 31, 2003</b>				
Debt securities	\$416,774	\$2,456	\$ 95	\$419,135
Equity securities	5,344	4,048	623	8,769
	<u>\$422,118</u>	<u>\$6,504</u>	<u>\$718</u>	<u>\$427,904</u>

Net unrealized gains on marketable securities are reported net of tax of \$1,278,000 and \$2,068,000 in fiscal 2004 and fiscal 2003, respectively.

Maturities of debt securities at fair value as of March 31, 2004 are as follows:

(in thousands)	
Mature within one year	\$ 78,530
Mature in one to five years	150,178
Mature in five years and later	<u>352,504</u>
	<u>\$581,212</u>

Gross gains of \$7,322,000, \$13,650,000 and \$1,263,000 and gross losses of \$813,000, \$821,000 and \$865,000 were realized during fiscal years 2004, 2003 and 2002, respectively.

#### Note 5. Intangible Assets

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

(in thousands)	Weighted Average Life (years)	Original Cost	Accumulated Amortization	Net Book Value
March 31, 2004				
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	<u>14,267</u>	<u>5,802</u>	<u>8,465</u>
		<u>\$241,035</u>	<u>\$107,217</u>	<u>133,818</u>
Intangible assets no longer subject to amortization:				
Trademarks				<u>783</u>
				<u>\$134,601</u>
March 31, 2003				
Amortized intangible assets:				
Patents and technologies	19	\$ 117,435	\$ 36,126	\$ 81,309
Product rights and licenses	12	107,273	48,301	58,972
Other	20	<u>14,267</u>	<u>5,075</u>	<u>9,192</u>
		<u>\$238,975</u>	<u>\$ 89,502</u>	<u>149,473</u>
Intangible assets no longer subject to amortization:				
Trademarks				<u>783</u>
				<u>\$150,256</u>

During fiscal 2004 and 2003, the Company removed from the balance sheet certain intangible assets with an original cost of \$2,440,000 and \$13,368,000, respectively. Such assets were fully amortized and have no ongoing benefit to current operations. Other intangibles consist principally of non-compete agreements, customer lists and contracts.

Amortization expense for fiscal years 2004, 2003 and 2002 was \$20,155,000, \$18,864,000 and \$26,382,000, respectively, and is expected to be \$18,195,000, \$14,204,000, \$13,845,000, \$13,362,000 and \$13,032,000 for fiscal years 2005 through 2009, respectively.

During fiscal 2004, the Company paid \$4,500,000 for intangible assets acquired as part of a licensing agreement for omeprazole.

#### Note 6. Other Assets

Other assets consist of the following components at March 31, 2004 and 2003:

(in thousands)	2004	2003
Cash surrender value	\$35,854	\$37,306
Pooled asset funds	—	6,316
Investments in and advances to Somerset	871	18,024
Other	10,493	24,199
	<u>\$47,218</u>	<u>\$85,845</u>

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.

Pooled asset funds represent our interest in limited liability partnership funds that invest in common and preferred stocks, bonds and money market funds. In fiscal 2001, we began to liquidate these investments in an effort to reduce the impact of market fluctuations. The total amounts liquidated in fiscal 2004 and fiscal 2003 were \$7,269,000 and \$17,804,000. As of March 31, 2004, the investment in the limited liability partnership fund was fully liquidated. We recorded our share of earnings or losses as other income or expense with the offsetting entry to the corresponding investment account. Earnings (losses) on the pooled asset funds included in other income amounted to \$1,766,000, (\$2,086,000) and \$7,113,000 in fiscal years 2004, 2003 and 2002, respectively. At March 31, 2003, the carrying amounts of these investments approximated fair value.

In November 1988, we acquired 50% of the outstanding common stock of Somerset Pharmaceuticals, Inc. ("Somerset"). We account 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 our 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 2004, 2003 and 2002. During fiscal 2004, we received a dividend of \$10,000,000 from Somerset. No dividends were received in fiscal 2003 or 2002.

Other assets at March 31, 2003, included an investment in a foreign entity which was accounted for using the cost method of accounting and had a carrying value of \$14,273,000. The balance at March 31, 2003, reflects a charge of \$5,727,000 recorded in the fourth quarter of fiscal 2003 to adjust the carrying value of this investment to its estimated fair value. During fiscal 2004, the Company sold its ownership interest in this foreign entity back to that entity for approximately \$15,000,000. According to the agreement, Mylan received \$5,000,000 in fiscal 2004 and will receive the remainder in fiscal 2005.

Based on a periodic review of other investments, excluding the investment in a foreign entity as discussed above, for other-than-temporary declines in fair value, we recorded adjustments of \$566,000 and \$1,821,000 in fiscal years 2003 and 2002, respectively, to reduce the carrying value of other assets to their estimated fair value. Such adjustments were recorded as reductions to other income.

## Note 7. Revolving Line of Credit

In March 2003, we renewed our agreement with a commercial bank for a revolving line of credit. This line of credit expires on July 31, 2004 and allows Mylan to borrow up to \$50,000,000, on an unsecured basis, at an interest rate based on the published daily London Interbank Offered Rate. At the Company's option, it may elect an alternative base rate as the interest rate by giving written notice to the lender. The agreement does not contain any significant financial covenants. At March 31, 2004 and 2003, we had no outstanding borrowings under this line of credit.

## Note 8. Long-Term Obligations

Long-term obligations consist of the following components at March 31, 2004 and 2003:

(in thousands)	2004	2003
Deferred compensation	\$17,307	\$18,351
Retirement benefits	2,974	2,901
Other	435	277
Total long-term obligations	20,716	21,529
Less: Current portion of long-term obligations	1,586	1,586
Long-term obligations, net of current portion	<u>\$19,130</u>	<u>\$19,943</u>

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.

## Note 9. Income Taxes

Income taxes consist of the following components:

(in thousands) Fiscal year ended March 31,	2004	2003	2002
Federal:			
Current	\$133,223	\$156,823	\$161,977
Deferred	<u>30,549</u>	<u>(18,127)</u>	<u>(32,150)</u>
	163,772	138,696	129,827
State and Puerto Rico:			
Current	12,501	17,211	20,809
Deferred	<u>1,726</u>	<u>(1,747)</u>	<u>(2,564)</u>
	14,227	15,464	18,245
Income taxes	<u>\$177,999</u>	<u>\$154,160</u>	<u>\$148,072</u>
Pretax earnings	<u>\$512,608</u>	<u>\$426,513</u>	<u>\$408,323</u>
Effective tax rate	<u>34.7%</u>	<u>36.1%</u>	<u>36.3%</u>

Temporary differences and carryforwards that result in the deferred tax assets and liabilities are as follows at March 31, 2004 and 2003:

(in thousands)	2004	2003
Deferred tax assets:		
Employee benefits	\$ 9,824	\$ 9,901
Contractual agreements	—	13,923
Intangible assets	9,721	10,058
Accounts receivable allowances	75,301	87,539
Inventories	1,852	3,810
Investments	8,099	9,077
Federal tax loss carryforwards	—	1,002
Tax credit carryforwards	570	3,175
Other	86	—
Total deferred tax assets	105,453	138,485
Deferred tax liabilities:		
Plant and equipment	19,271	10,682
Intangible assets	27,915	33,048
Investments	2,394	3,688
Other	—	71
Total deferred tax liabilities	49,580	47,489
Deferred tax asset, net	\$ 55,873	\$ 90,996
Classification in the Consolidated Balance Sheets:		
Deferred income tax benefit – current	\$ 78,477	\$104,173
Deferred income tax liability – noncurrent	22,604	13,177
Deferred tax asset, net	\$ 55,873	\$ 90,996

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 certain limitations set forth in the Internal Revenue Code. In fiscal 2004, we utilized the remainder of the acquired net operating loss carryforward of \$2,707,000 to reduce the tax liability. In fiscal 2003, we utilized approximately \$10,709,000 of the acquired federal net operating loss carryforwards to reduce our tax liability. Acquired federal tax credit carryforwards of \$2,092,000 at March 31, 2003 were fully utilized in fiscal 2004.

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,	2004	2003	2002
Statutory tax rate	35.0%	35.0%	35.0%
State and Puerto Rico income taxes, net	2.0%	2.6%	2.8%
Nondeductible amortization	0.0%	0.2%	0.6%
Tax credits	(1.8%)	(1.8%)	(2.1%)
Other items	(0.5%)	0.1%	0.0%
Effective tax rate	34.7%	36.1%	36.3%

Tax credits result principally from operations in Puerto Rico and from qualified research and development expenditures, including orphan drug research. State income taxes are shown net of the federal deduction benefit.

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 \$4,732,000 each year in fiscal 2004, 2003 and 2002.

Our federal income tax returns have been audited by the Internal Revenue Service through fiscal 2000.

#### **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 Board adopted a Shareholder Rights Plan (the “Rights Plan”) in fiscal 1996 to provide our Board with sufficient time to assess and evaluate any takeover bid and explore and develop a reasonable response. Effective November 1999, the Rights Plan was amended to eliminate the special rights held by continuing directors. The Rights Plan will expire on September 5, 2006 unless it is extended or such rights are earlier redeemed or exchanged.

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. The purchase of common stock under this program was at market prices. In fiscal 2004 and 2003, 6,458,700 and 16,041,300 shares of common stock were purchased for approximately \$133,088,000 and \$240,541,000, respectively. The Stock Repurchase Program was completed on November 18, 2003.

On July 25, 2003, the Company’s shareholders approved an increase in the number of authorized shares of common stock to 600,000,000 from 300,000,000.

**Note 11. Stock Option Plan**

In 1997, the Board adopted and the shareholders approved the *Mylan Laboratories Inc. 1997 Incentive Stock Option Plan* (the “1997 Plan”). Under the 1997 Plan, up to 33,750,000 shares of the Company’s common stock were available for grant to employees, non-employee directors, and consultants, agents and advisors as either incentive stock options or nonqualified stock options. Options, which were granted at not less than fair market value on the date of the grant, may be exercised within ten years from the date of grant. Options generally vest over three, four and five years.

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. The remaining 5,350,000 shares that had been reserved for the issuance of options under the 1997 Plan were removed from reserve.

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 2004 was \$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 Shares Under Option	Weighted Average Exercise Price per Share
Outstanding at March 31, 2001	16,154,073	\$ 9.43
Options granted	8,264,247	11.74
Options exercised	(3,399,223)	6.93
Options forfeited	(1,754,206)	11.24
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

The following table summarizes information about stock options outstanding as of March 31, 2004:

Ranges of Exercise Price per Share	Options Outstanding			Options Exercisable	
	Number of Shares	Average Life <sup>(1)</sup>	Average Price <sup>(2)</sup>	Number of Shares	Average Price <sup>(2)</sup>
\$ 4.08 - \$ 11.34	5,054,820	6.15	\$10.25	4,861,325	\$10.24
11.48 - - 11.48	4,323,439	7.20	11.48	2,609,424	11.48
11.58 - - 13.40	4,441,702	7.23	12.26	3,493,511	12.15
13.42 - - 19.17	3,473,781	8.51	15.78	1,614,912	14.52
19.36 - - 28.16	5,536,166	9.04	19.65	777,044	19.36
\$ 4.08 - - \$ 28.16	<u>22,829,908</u>	7.62	\$13.99	<u>13,356,216</u>	\$12.03

(1) Weighted average contractual life remaining in years.

(2) Weighted average exercise price per share.

The number of shares exercisable and the associated weighted average exercise price as of March 31, 2003 was 9,908,871 shares at \$11.03 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 2004, 2003 and 2002, using the Black-Scholes option pricing model, and the assumptions used are as follows:

Fiscal year ended March 31,	2004	2003	2002
Volatility	41.1%	44.0%	48.0%
Risk-free interest rate	2.7%	3.1%	4.8%
Dividend yield	0.4%	0.5%	0.6%
Expected term of options (in years)	6.5	6.0	5.4
Weighted average fair value per option	\$8.51	\$7.36	\$5.56

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.

In consideration for the exercise of stock options, we received and recorded into treasury stock 22,818 shares valued at \$344,000 in fiscal 2003, and 182,520 shares valued at \$2,716,000 in fiscal 2002. No such amounts were received in fiscal 2004.

## 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, 2004 and 2003.

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 2004, 2003 and 2002 were \$11,927,000, \$11,707,000 and \$9,756,000, 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 25% of the Company's total workforce at March 31, 2004.

### **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 U.S. Food and Drug Administration ("FDA") through the Abbreviated New Drug Application ("ANDA") process. Two customers accounted for 21% and 11%, respectively, of Generic Segment net revenues in fiscal 2004.

Brand pharmaceutical products are generally new, patent-protected products marketed directly to health care professionals. These products are approved by the 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 generics which are responsive to promotional efforts. Three customers accounted for 27%, 22% and 13%, respectively, of Brand Segment revenues in fiscal 2004.

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:

<b>(in thousands)</b> <b>Fiscal year ended March 31,</b>	<b>2004</b>	<b>2003</b>	<b>2002</b>
<b>Total revenues</b>			
Generic	\$1,096,128	\$1,012,617	\$ 971,075
Brand	278,489	256,575	132,975
Consolidated	<u>\$1,374,617</u>	<u>\$1,269,192</u>	<u>\$1,104,050</u>
<b>Depreciation and amortization expense</b>			
Generic	\$ 21,996	\$ 19,607	\$ 20,365
Brand	17,495	17,555	17,336
Corporate/Other	4,832	3,418	8,410
Consolidated	<u>\$ 44,323</u>	<u>\$ 40,580</u>	<u>\$ 46,111</u>
<b>Segment profit (loss)</b>			
Generic	\$ 510,821	\$ 454,043	\$ 483,068
Brand	46,521	32,682	(16,212)
Corporate/Other	(44,734)	(60,212)	(58,533)
Consolidated	<u>\$ 512,608</u>	<u>\$ 426,513</u>	<u>\$ 408,323</u>
<b>Property, plant and equipment additions</b>			
Generic	\$ 37,777	\$ 25,400	\$ 14,313
Brand	16,260	5,335	5,369
Corporate/Other	64,414	1,860	939
Consolidated	<u>\$ 118,451</u>	<u>\$ 32,595</u>	<u>\$ 20,621</u>
<b>March 31,</b>	<b>2004</b>	<b>2003</b>	<b>2002</b>
<b>Segment assets</b>			
Generic	\$ 677,450	\$ 536,171	\$ 470,405
Brand	198,142	213,016	209,603
Corporate/Other	999,698	996,036	939,872
Consolidated	<u>\$1,875,290</u>	<u>\$1,745,223</u>	<u>\$1,619,880</u>

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

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

<b>(in thousands)</b> <b>Fiscal year ended March 31,</b>	<b>2004</b>	<b>2003</b>	<b>2002</b>
Cardiovascular	\$ 600,238	\$ 622,911	\$ 434,909
Central nervous system	330,081	335,041	454,802
Dermatology	102,513	87,369	20,550
Gastrointestinal	137,743	27,356	25,395
Other <sup>1</sup>	204,042	196,515	168,394
	<u>\$1,374,617</u>	<u>\$1,269,192</u>	<u>\$1,104,050</u>

<sup>1</sup> 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 us 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 our sales force and key employees. For fiscal years 2004, 2003 and 2002, The Company made lease payments of \$3,136,000, \$5,640,000 and \$4,812,000, respectively.

Future minimum lease payments under these commitments are as follows:

(in thousands) Fiscal	Operating Leases
2005	\$ 4,922
2006	3,271
2007	2,039
2008	1,818
2009	169
Thereafter	387
	<u>\$12,606</u>

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 \$8,500,000 would be paid over the next five years.

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. Additionally, we have 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.

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

In July 2002, the Company terminated an agreement with a consulting firm that had been controlled by Mylan's Chief Executive Officer. This agreement was terminated prior to the Chief Executive Officer accepting his position with Mylan. Under the agreement, the consulting firm provided strategic advisory services to Mylan. While the agreement was in effect during fiscal years 2003 and 2002, the consulting firm was paid \$380,000 and \$1,565,000, respectively.

Mylan holds an equity interest in a supplier. During fiscal years 2004, 2003 and 2002, Mylan paid \$5,651,000, \$3,715,000 and \$18,287,000, respectively, to the supplier in return for certain raw materials used in production and \$901,000, \$2,727,000 and \$330,000 in fiscal 2004, 2003 and 2002, respectively, for royalties under a product licensing agreement with this supplier.

A director of the Company is the chief executive officer of a bank in which the Company had on deposit \$10,011,000 in a money market account

representing 4% of the bank's total deposits at March 31, 2003. There were no amounts on deposit at March 31, 2004.

In February 2003, a director of the Company, who also became an officer of the Company in March 2002, terminated an "of counsel" relationship he had with a law firm that has been providing legal services to the Company for over 15 years. Fees paid to that firm for legal services rendered to the Company totaled \$6,302,000 and \$3,325,000 in fiscal years 2003 and 2002, respectively.

#### **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. No amounts have been accrued at March 31, 2004, with respect to any of these unsettled cases.

##### ***Omeprazole***

In fiscal 2001, Mylan Pharmaceuticals Inc. ("MPI") filed an ANDA seeking approval from the FDA to manufacture, market and sell omeprazole delayed-release capsules, and made "Paragraph IV" certifications to several patents owned by AstraZeneca PLC ("AstraZeneca") that were listed in the FDA's "Orange Book". AstraZeneca filed suit against MPI and Mylan Laboratories Inc. ("Mylan") in the U.S. District Court for the Southern District of New York alleging infringement of several of AstraZeneca's patents. MPI filed a motion for summary judgment as to all claims of infringement, and the summary judgment motion remains 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 announced that MPI had commenced the sale of omeprazole 10 mg and 20 mg delayed-release capsules. AstraZeneca then amended the pending lawsuit to assert claims against Mylan and MPI, and filed a separate lawsuit against MPI's supplier, Esteve Quimica S.A. ("Esteve"), for unspecified money damages and a finding of willful infringement which could result in treble damages, injunctive relief, attorneys' fees, costs of litigation and such further relief as the court deems just and proper.

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. The '875 Patent was issued to Esteve and licensed to MPI. Esteve joined the suit as a co-plaintiff with MPI in December 2002. 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 had not been asserted in the Delaware action. KUDCo and the individual allege that the individual is the sole inventor of the '875 Patent, that the individual owns the '875 Patent and has assigned his ownership interest in the '875 Patent to KUDCo, and that MPI and Esteve are infringing the '875 Patent. The new lawsuit seeks an order directing that the individual be listed as the sole inventor or a co-inventor of the '875 Patent and enjoining MPI from infringing the '875 Patent, together with costs and attorneys' fees.

### ***Paclitaxel***

In June 2001, NAPRO Biotherapeutics Inc. (“NAPRO”) and Abbott Laboratories Inc. (“Abbott”) filed suit against Mylan, MPI and UDL in the U.S. District Court for the Western District of Pennsylvania. Plaintiffs allege that the manufacture, use and sale of MPI’s paclitaxel product, which MPI began selling in July 2001, infringes certain patents owned by NAPRO and allegedly licensed to Abbott. Plaintiffs seek unspecified damages plus interest, a finding of willful infringement which could result in treble damages, injunctive relief, attorneys’ fees, costs of litigation and such equitable and other relief as the court deems just and proper. In December 2003, the district court entered a final judgment against Mylan, MPI and UDL, finding that the defendants infringed valid and enforceable patents. The Company has appealed these rulings to the U.S. Court of Appeals for the Federal Circuit. A trial is scheduled for February 2005 to address the plaintiffs’ claims for money damages and a finding of willful infringement, which could result in treble damages, attorneys’ fees and costs of litigation being assessed against the Company.

Also in December 2003, NAPRO filed a motion for a permanent injunction seeking to prohibit the Company from, among other things, making, using, licensing or selling any paclitaxel product that infringes NAPRO’s patents. The district court granted the motion although, recognizing the Company’s intention to immediately appeal the ruling, granted a temporary stay of the injunction. The Company filed an emergency motion with the Federal Circuit requesting a stay of the injunction until the appeal is resolved, arguing that equities favored a stay. In February 2004, the Federal Circuit granted the Company’s motion.

### ***Pricing and Medicaid Litigation***

Mylan, along with a number of other pharmaceutical manufacturers, was named as a defendant in four lawsuits filed in the state courts of California in which the plaintiffs alleged the defendants unlawfully, unfairly and fraudulently manipulated the reported average wholesale price of various products, allegedly to increase third-party reimbursements to others for their products. All of these lawsuits have been voluntarily dismissed by the plaintiffs.

On September 26, 2003, the Commonwealth of Massachusetts sued Mylan and 12 other generic drug companies alleging unlawful manipulation of reimbursements under the Massachusetts Medicaid program. All defendants have filed a motion to dismiss the case, which remains pending.

### ***Mirtazapine***

In fiscal 2004, Mylan 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 and MPI by summary judgment in December 2002.

### ***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***

***Nifedipine***

In February 2001, Biovail Laboratories Inc. (“Biovail”) filed suit against Mylan, 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 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 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. This settlement does not include several related cases, and the Company does not believe that an adverse result in any of the remaining lorazepam and clorazepate cases, collectively or individually, would have a material adverse effect on the Company’s financial position or results of operations.

***Zagam®***

Mylan, Mylan Caribe Inc. and Bertek Pharmaceuticals, Inc. (“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.

***Other Inquiries***

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. Several states' Attorneys General ("AGs") have also sent letters to MPI, UDL and Bertek demanding that those companies retain documents relating to Medicaid reimbursement and rebate calculations pending the outcome of unspecified investigations by those AGs into such matters.

**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, 2004 and 2003, and the related consolidated statements of earnings, shareholders' equity and cash flows for each of the three years in the period ended March 31, 2004. 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, 2004 and 2003, and the results of their operations and their cash flows for each of the three years in the period ended March 31, 2004, in conformity with accounting principles generally accepted in the United States of America. Also, in our opinion, such financial statement schedule, when considered in relation to the basic consolidated financial statements taken as a whole, presents fairly in all material respects the information set forth therein.

As discussed in Note 2 to the Consolidated Financial Statements, the Company changed its method of accounting for goodwill effective April 1, 2002.

Deloitte & Touche LLP  
Pittsburgh, Pennsylvania  
May 18, 2004

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**Mylan Laboratories Inc.**  
**Supplementary Financial Information**
**Quarterly Financial Data**

(unaudited, in thousands, except per share data)

	1st Quarter	2nd Quarter	3rd Quarter	4th Quarter	Year
<b>Fiscal 2004</b>					
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
<b>Fiscal 2003</b>					
Total revenues	\$275,473	\$319,539	\$320,494	\$353,686	\$1,269,192
Gross profit	147,602	166,732	169,576	187,526	671,436
Net earnings	61,849	68,229	68,432	73,843	272,353
Earnings per share:					
Basic	\$ 0.22	\$ 0.24	\$ 0.25	\$ 0.27	\$ 0.98
Diluted	\$ 0.21	\$ 0.24	\$ 0.24	\$ 0.27	\$ 0.96
Share prices <sup>(2)</sup> :					
High	\$ 14.18	\$ 15.08	\$ 15.51	\$ 19.36	\$ 19.36
Low	\$ 11.18	\$ 12.22	\$ 13.15	\$ 15.77	\$ 11.18

(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 our 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, 2004. 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.

### **PART III**

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

Certain information required by this Item is set forth under the captions "Item 1 – Election of Directors", "Executive Officers" and "Security Ownership of Certain Beneficial Owners and Management – Section 16(a) Beneficial Ownership Reporting Compliance" in our 2004 Proxy Statement and is incorporated herein by reference.

##### *Code of Ethics*

The Company has adopted a Code of Ethics that applies to our Chief Executive Officer, Chief Financial Officer and 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 our website.

#### **ITEM 11. Executive Compensation**

The information required by this Item is set forth under the caption "Executive Compensation" in our 2004 Proxy Statement and is incorporated herein by reference.

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

The information required by this Item is set forth under the captions "Security Ownership of Certain Beneficial Owners and Management" and "Executive Compensation – Equity Compensation Plan Information" in our 2004 Proxy Statement and is incorporated herein by reference.

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

The information required by this Item is set forth under the caption "Certain Relationships and Related Transactions" in our 2004 Proxy Statement and is incorporated herein by reference.

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

The information required by this Item is set forth under the caption "Independent Auditors" in our 2004 Proxy Statement and is incorporated herein by reference.

## PART IV

### ITEM 15. Exhibits, Financial Statement Schedules, and Reports on Form 8-K

#### (a) 1. Consolidated Financial Statements

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

#### 2. Financial Statement Schedules

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

Description	Beginning Balance	Additions/Deductions charged to costs and expenses	Deductions	Ending Balance
Allowance for Doubtful Accounts:				
Fiscal Year Ended				
March 31, 2004	\$8,438	\$2,325	\$4,798	\$5,965
March 31, 2003	\$6,622	\$2,772	\$ 956	\$8,438
March 31, 2002	\$5,049	\$4,270	\$2,697	\$6,622

#### 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    | By-laws of the registrant, as amended to date, filed as Exhibit 3.2 to Form 10-Q for the quarter ended September 30, 2003, and incorporated herein by reference.  |
| 4.1(a) | Rights Agreement dated as of August 22, 1996, between the registrant and American Stock Transfer & Trust Co., 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   |

Co., filed as Exhibit 1 to Form 8-A/A, filed with the SEC on March 31, 2000.

- 10.1 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.\*
- 10.3 Mylan Laboratories Inc. 1992 Nonemployee Director Stock Option Plan, as amended to date, filed as Exhibit 10(l) to Form 10-K for the fiscal year ended March 31, 1998, and incorporated herein by reference.\*
- 10.4(a) Executive Employment Agreement with Stuart A. Williams dated March 1, 2002, filed as Exhibit 10.5 to Form 10-K for the fiscal year ended March 31, 2002, and incorporated herein by reference.\*
- 10.4(b) Amendment No. 1 to Executive Employment Agreement dated as of December 15, 2003, between Mylan Laboratories Inc. and Stuart A. Williams, filed as Exhibit 10.4(a) to Form 10-Q for the quarter ended December 31, 2003, and incorporated herein by reference.\*
- 10.5(a) Executive Employment Agreement with Edward J. Borkowski dated March 4, 2002, filed as Exhibit 10.6 to Form 10-K for the fiscal year ended March 31, 2002, and incorporated herein by reference.\*
- 10.5(b) Amendment No. 1 to Executive Employment Agreement dated as of December 15, 2003, between Mylan Laboratories Inc. and Edward J. Borkowski, filed as Exhibit 10.5(a) to Form 10-Q for the quarter ended December 31, 2003, and incorporated herein by reference.\*
- 10.6 Salary Continuation Plan with C.B. Todd dated January 27, 1995, filed as Exhibit 10(b) to Form 10-K for the fiscal year ended March 31, 1995, and incorporated herein by reference.\*
- 10.7 Salary Continuation Plan with Louis J. DeBone dated March 14, 1995, filed as Exhibit 10(c) to Form 10-K for the fiscal year ended March 31, 1995, and incorporated herein by reference.\*
- 10.8 Salary Continuation Plan with John P. O'Donnell dated March 14, 1995, as amended to date, filed as Exhibit 10.9 to Form 10-K for the fiscal year ended March 31, 2001, and incorporated herein by reference.\*
- 10.9 Salary Continuation Plan with Milan Puskar dated January 27, 1995, as amended, and Patricia Sunseri dated March 14, 1995, as amended, filed as Exhibit 10.1 to Form 10-Q for the quarter ended September 30, 2001, and incorporated herein by reference.\*

10.10	Split Dollar Life Insurance Arrangement with 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.*
10.11	Service Benefit Agreement with Laurence S. DeLynn and John C. Gaisford, M.D., each dated January 27, 1995, and filed as Exhibit 10(g) to Form 10-K for fiscal year ended March 31, 1995, and incorporated herein by reference.*
10.12	Transition and Succession Agreement dated November 10, 1999, as amended to date, with Patricia Sunseri, Louis J. DeBone and John P. O'Donnell, filed as Exhibit 10.2 to Form 10-Q for the quarter ended December 31, 2001, and incorporated herein by reference.*
10.13	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.*
10.14	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.*
10.15(a)	Executive Employment Agreement with Robert J. Coury, dated July 22, 2002, filed as Exhibit 10.1 to Form 10-Q for the quarter ended June 30, 2002, and incorporated herein by reference.*
10.15(b)	Amendment No. 1 to Executive Employment Agreement dated as of December 15, 2003, between Mylan Laboratories Inc. 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.*
10.16(a)	Executive Employment Agreement with Louis J. DeBone, dated July 22, 2002, filed as Exhibit 10.2 to Form 10-Q for the quarter ended June 30, 2002, and incorporated herein by reference.*
10.16(b)	Amendment No. 1 to Executive Employment Agreement dated as of December 15, 2003, between Mylan Laboratories Inc. and Louis J. DeBone, filed as Exhibit 10.16(a) to Form 10-Q for the quarter ended December 31, 2003, and incorporated herein by reference.*
10.17(a)	Executive Employment Agreement with John P. O'Donnell, dated July 22, 2002, filed as Exhibit 10.3 to Form 10-Q for the quarter ended June 30, 2002, and incorporated herein by reference.*
10.17(b)	Amendment No. 1 to Executive Employment Agreement dated as of December 15, 2003, between Mylan Laboratories Inc. and John P. O'Donnell, filed as Exhibit 10.17(a) to Form 10-Q for the quarter ended December 31, 2003, and incorporated herein by reference.*
10.18	Form of Employment Agreement dated as of December 15, 2003, between Mylan Laboratories Inc. and each of Mark W. Fitch,



	Frank R. Sisto and Gary E. Sphar, filed as Exhibit 10.18 to Form 10-Q for the quarter ended December 31, 2003, and incorporated herein by reference.*
10.19	Transition and Succession Agreement dated as of December 15, 2003, between Mylan Laboratories Inc. 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.*
10.20	Transition and Succession Agreement dated as of December 15, 2003, between Mylan Laboratories Inc. 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.*
10.21	Transition and Succession Agreement dated as of December 15, 2003, between Mylan Laboratories Inc. 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.*
10.22	Transition and Succession Agreement dated as of December 15, 2003, between Mylan Laboratories Inc. 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.*
10.23	Transition and Succession Agreement dated as of December 15, 2003, between Mylan Laboratories Inc. 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.*
10.24	Form of Transition and Succession Agreement dated as of December 15, 2003, between Mylan Laboratories Inc. and each of Mark W. Fitch, Frank R. Sisto and Gary E. Sphar, filed as Exhibit 10.24 to Form 10-Q for the quarter ended December 31, 2003, and incorporated herein by reference.*
10.25	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.*
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.

*(b) Reports on Form 8-K*

On January 29, 2004, the Company filed a Report on Form 8-K regarding the release of earnings for the three and nine months ended December 31, 2003.

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On March 3, 2004, the Company filed a Report on Form 8-K regarding a presentation to investors.

On March 26, 2004, the Company filed a Report on Form 8-K regarding correspondence submitted to the FDA with regard to the Company's finally approved ANDA for its generic transdermal fentanyl product.

## 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 June 11, 2004.

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 June 11, 2004.

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/ JOHN C. GAISFORD, M.D.	Director
John C. Gaisford, M.D.	
/s/ DOUGLAS J. LEECH	Director
Douglas J. Leech	
/s/ JOSEPH C. MAROON, M.D.	Director
Joseph C. Maroon, M.D.	
/s/ PATRICIA A. SUNSERI	Director
Patricia A. Sunseri	

Signature	Title
<div>/s/ C.B. TODD</div> <div>C.B. Todd</div>	Director
<div>/s/ R.L. VANDERVEEN, PH.D., R.PH.</div> <div>R.L. Vanderveen, Ph.D., R.Ph.</div>	Director
<div>/s/ STUART A. WILLIAMS, ESQ.</div> <div>Stuart A. Williams, Esq.</div>	Director

EXHIBIT INDEX

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Subsidiaries

Name	State of Organization
Mylan Pharmaceuticals Inc.	West Virginia
Milan Holding Inc.	Vermont
Bertek Pharmaceuticals Inc.	Texas
Mylan Inc.	Delaware
UDL Laboratories, Inc.	Illinois
Mylan Technologies Inc.	West Virginia
American Triumvirate Insurance Company	Vermont
Mylan International Holdings, Inc.	Vermont
Mylan Caribe, Inc.	Vermont
MLRE LLC	Pennsylvania

## CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Registration Statements Nos. 333-35887, 333-42182, 333-43081, 333-65327, 333-65329, 333-98811, 333-111076 and 333-111077 of Mylan Laboratories Inc. on Form S-8 of our report dated May 18, 2004, which report expresses an unqualified opinion and includes an explanatory paragraph relating to Mylan Laboratories Inc.'s change in method of accounting for goodwill in fiscal 2003, appearing in this Annual Report on Form 10-K of Mylan Laboratories Inc. for the year ended March 31, 2004.

/s/ Deloitte & Touche LLP

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DELOITTE & TOUCHE LLP  
Pittsburgh, Pennsylvania  
June 11, 2004

**Certification of CEO Pursuant to  
Section 302 of the Sarbanes-Oxley Act of 2002**

I, Robert J. Coury, certify that:

1. I have reviewed this annual report on Form 10-K of Mylan Laboratories Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the period[s] presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
  - a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - c) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):
  - a) all significant deficiencies and material weaknesses in the design or operation of internal controls over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: June 11, 2004

/s/ Robert J. Coury

Robert J. Coury  
Chief Executive Officer



**Certification of CFO Pursuant to  
Section 302 of the Sarbanes-Oxley Act of 2002**

I, Edward J. Borkowski, certify that:

1. I have reviewed this annual report on Form 10-K of Mylan Laboratories Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the period[s] presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
  - a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - c) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):
  - a) all significant deficiencies and material weaknesses in the design or operation of internal controls over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: June 11, 2004

/s/ Edward J. Borkowski

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Edward J. Borkowski  
Chief Financial Officer

**CERTIFICATIONS of CEO and CFO PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Annual Report on Form 10-K of Mylan Laboratories Inc. (the "Company") for the year ended March 31, 2004 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of the undersigned, in the capacities and on the date indicated below, hereby certifies pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to his knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: June 14, 2004

/s/ Robert J. Coury

\_\_\_\_\_  
Robert J. Coury  
Chief Executive Officer

/s/ Edward J. Borkowski

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Edward J. Borkowski  
Chief Financial Officer

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

The foregoing certification is being furnished in accordance with Securities and Exchange Commission Release No. 34-47551 and shall not be considered filed as part of the Form 10-K.