BWAY CORP Form 10-K December 30, 2002 Table of Contents

# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

# **FORM 10-K**

# x ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended September 29, 2002

OR

# " TRANSITION REPORT PURSUANT TO SECTION 13 OR 15 (d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from\_\_\_\_\_to\_\_\_\_

**Commission File Number 1-12415** 

# **BWAY CORPORATION**

(Exact name of registrant as specified in its charter)

**Delaware** (State of incorporation) 36-3624491 (I.R.S. Employer Identification No.)

8607 Roberts Drive, Suite 250 Atlanta, Georgia 30350 (Address of principal executive offices)

770-645-4800 (Registrant s telephone number)

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

Common Stock, par value \$0.01 per share, registered on the New York Stock Exchange.

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

None

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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 x 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.

The aggregate market value of the voting and non-voting common equity held by non-affiliates computed as of December 19, 2002 was approximately \$172,421,577 (based upon the closing price for shares of the registrant s common stock as quoted on the New York Stock Exchange as of that date).

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Act). Yes x No "

The aggregate market value of the voting and non-voting common equity held by non-affiliates computed as of March 28, 2002 was approximately \$109,670,389 (based upon the closing price for shares of the registrant s common stock as quoted on the New York Stock Exchange as of that date, which is the last business day of the New York Stock Exchange preceding the registrant s most recently completed second fiscal quarter).

As of December 19, 2002, there were 8,761,259 shares of BWAY Corporation s Common Stock outstanding.

#### DOCUMENTS INCORPORATED BY REFERENCE

None.

#### **BWAY CORPORATION**

### TABLE OF CONTENTS

PART I		
Item 1.	Business	1
Item 2.	Properties	7
Item 3.	Legal Proceedings	7
Item 4.	Submission of Matters to a Vote of Security Holders	8
PART II		
Item 5.	Market for the Registrant s Common Equity and Related Stockholder Matters	8
Item 6.	Selected Financial Data	8
Item 7.	Management s Discussion and Analysis of Financial Condition and Results of Operation	11
Item 7A.	Quantitative and Qualitative Disclosures about Market Risk	17
Item 8.	Financial Statements and Supplementary Data	17
Item 9.	Changes in and Disagreements With Accountants on Accounting and Financial Disclosure	17
PART III		
Item 10.	Directors and Executive Officers of the Registrant	17
Item 11.	Executive Compensation	20
Item 12.	Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	31
Item 13.	Certain Relationships and Related Transactions	33
Item 14.	Controls and Procedures	33
PART IV		
Item 15.	Exhibits, Financial Statement Schedules, and Reports on Form 8-K	34

ii

Page

#### **BWAY CORPORATION AND SUBSIDIARIES**

#### FORM 10-K ANNUAL REPORT

#### FOR THE FISCAL YEAR ENDED SEPTEMBER 29, 2002

#### PART I

#### Item 1. Business

#### General

BWAY Corporation, including all of its subsidiaries (hereinafter BWAY, the Company, we, our or us ), is the leading North American manufacturer of steel containers for paint, coffee and certain other consumer and industrial products. Our product offerings include a wide variety of steel containers such as paint, coffee, aerosol and specialty cans which are used by our customers to package a diverse range of end-use products which, in addition to paint and coffee, include household and personal care products, automotive after-market products, paint thinners and driveway and deck sealants. We also provide our customers with metal shearing, coating and printing services through our material center services business. Our end-use markets have historically exhibited stable demand characteristics and our customer base includes leading participants in these markets. The references in this report to market positions or market share are based on information derived from annual reports, trade publications and management estimates, which we believe are reliable.

We are the successor to a business founded in 1875. In January 1989, we were purchased from Owens-Illinois Corporation in a leveraged transaction led by our then existing management and other industry investors. In June 1995, we completed our initial public offering and, since November 1996, have been listed on the New York Stock Exchange.

#### Agreement and Plan of Merger

On September 30, 2002, BWAY, BCO Holding Company (BCO Holding), an affiliate of Kelso & Company, L.P. (Kelso), and BCO Acquisition, Inc. (BCO Acquisition), a wholly-owned subsidiary of BCO Holding, entered into an Agreement and Plan of Merger (the Merger Agreement), which provides for the merger (the Merger) of BCO Acquisition and BWAY, with BWAY continuing as the surviving corporation. Upon completion of the Merger and related transactions, we will be controlled by affiliates of Kelso, which is a private investment firm founded in 1971. The Merger is subject to approval by our stockholders, the availability of certain financing, and other customary conditions. We anticipate completing the Merger prior to February 28, 2003, although we cannot provide assurance that we will be able to do so.

The following transactions are expected to occur in connection with the Merger: (1) approximately 8.1 million shares of our common stock will be converted into the right to receive \$20.00 per share in cash; (2) options to purchase approximately 1.1 million shares of our common stock will be canceled in exchange for lump sum payments in cash of \$20.00 per underlying share, less the applicable option exercise price; (3) affiliates of Kelso will contribute cash in exchange for shares representing approximately 73.9% of BCO Holding s fully diluted common stock following the transactions; (4) certain stockholders of BWAY, including members of management, will exchange certain of their shares and options in BWAY in exchange for the balance of BCO Holding s fully diluted common stock following the transactions; (5) we will either amend and restate our credit facility or enter into a new credit facility; and (6) we will assume the obligations of BWAY Finance Corp. under the notes and related indenture for \$200 million 10% senior subordinated notes due 2010. BWAY Finance Corp. is a subsidiary of BCO Holding. As of the consummation of the Merger and the assumption of the \$200 million 10% senior subordinated notes due 2010, BWAY Manufacturing, Inc., a wholly-owned subsidiary of BWAY Corporation, will guarantee the \$200 million 10% senior subordinated notes due 2010.

If the Merger and assumption of the \$200 million 10% senior subordinated notes due 2010 are not completed by April 7, 2003, or the Merger Agreement is terminated before that date, BWAY Finance Corp. will be required to redeem the notes at a redemption price of 101% plus accrued and unpaid interest to the redemption date. In connection with the issuance of the \$200 million 10% senior subordinated notes due 2010 and pursuant to the terms of the Merger Agreement, we made available \$3.0 million to BWAY Finance, Corp. for deposit into escrow, representing a portion of the amount sufficient to cover the redemption premium and accrued interest.

We will use the net proceeds from these equity and debt financings to: (1) fund the cash consideration payable to its stockholders and option holders under the Merger Agreement; (2) repurchase or redeem all of our outstanding 10<sup>1</sup>/<sub>4</sub>% senior subordinated notes due 2007; (3) repay any outstanding principal and accrued interest under our credit facility as of the closing of the Merger; and (4) pay related transaction fees and expenses.

Upon completion of the Transactions (as defined below), we will become a private company and our common stock will be delisted from the New York Stock Exchange.

The Merger, the investment by affiliates of Kelso, the investment by certain stockholders and option holders who are exchanging shares and options, the new credit facility, the \$200 million 10% senior subordinated notes due 2010 and the application of the net proceeds therefrom, the purchase and redemption of our outstanding 10¼% senior subordinated notes due 2007, and the repayment of any outstanding principal and accrued interest under our credit facility are collectively referred to herein as the Transactions.

In the event the Merger Agreement is terminated and subject to the adjustments described in the last sentence of this paragraph, we have agreed to pay Kelso a \$6 million termination fee if the Merger Agreement is terminated under certain circumstances as described in the Merger Agreement. In addition, subject to such adjustments, we have agreed to reimburse Kelso for all of its out-of-pocket expenses of Kelso and its affiliates (including fees and expenses of financial advisors, outside legal counsel and accountants) incurred in connection with the Merger and the proposed financing of the Merger up to a maximum amount of \$4 million if the Merger Agreement is terminated under certain circumstances described in the Merger Agreement. However, under the terms of the Merger Agreement, because the escrow closing of \$200 million 10% senior subordinated notes due 2010 has occurred, the termination fee that may become payable has been reduced to \$3 million (instead of \$6 million) and the maximum amount of any of Kelso s expenses payable has been increased to \$7 million (instead of \$4 million).

#### Acquisitions and Dispositions

In November 1998, we acquired substantially all of the assets and assumed certain of the liabilities of the United States Can Company s metal services operations (the U.S. Can Acquisition ). The purchase price was approximately \$27.7 million in cash after adjustments for working capital. The acquisition included three operating plants and one non-operating plant. The acquired facilities operated two different businesses, material center services, which are part of our core business, and tinplate metal services, which are not a part of our business. The purchase method of accounting was used to establish and record a new cost basis for the assets acquired and liabilities assumed, and operating results for this acquisition have been included in our consolidated financial statements since the date of acquisition.

In November 1998, management committed to a plan to exit certain activities of the acquired facilities and integrate acquired assets and businesses with other of our facilities. In connection with the recording of the purchase, we established a reorganization liability of approximately \$11 million.

In November 1998, we signed a binding letter of intent to sell the acquired tinplate metal services business. The tinplate metal services business primarily purchases, processes, and sells nonprime steel to third party customers. Anticipating the sale of the tinplate metal services business, we closed the Brookfield, Ohio location in March 1999 and closed the Chicago Metal operations in September 1999. We finalized the sale of the tinplate services business to Arbon Steel and Service Company in the fourth quarter of fiscal 1999. In fiscal 1999, we excluded from results of operations the tinplate metal services business losses of \$4.4 million, including interest expense of \$0.7 million.

In the fourth quarter of fiscal 2000, we also closed the Chicago, Illinois material center services operation and transferred the work to other of our material center services facilities.

In June 2001, we implemented a restructuring plan. As part of that plan, redundant equipment at our manufacturing facilities in Elizabeth, New Jersey and Garland, Texas were taken out of service and the facilities were closed in September 2001. The existing business serviced by those facilities was primarily transferred to our Dallas, Texas and York, Pennsylvania facilities. In August 2002, due to unusually high demand for certain of our products, the previously closed Garland, Texas facility was partially utilized to manufacture goods to meet this demand. We expect to terminate production at the Garland facility when demand returns to normal. Additionally, we are examining the capacity potential of our other manufacturing facilities to handle additional volume.

#### **Industry Overview**

Metal containers are currently utilized for three primary markets: beverage, food and general line. The general line market includes paint cans, aerosol cans, oblong cans, steel pails and a variety of specialty cans. We estimate, based on industry data published by the Can Manufacturers Institute and the United States Bureau of Statistics, that 2001 industry shipments in the United States totaled approximately 101 billion units to the beverage market, 31 billion units to the food market and four billion units to the general line market. General line cans generally have higher selling prices than food or beverage cans. Few companies compete in all three product markets, and most of the companies which produce beverage and food cans do not compete in the general line market.

#### **Products and Markets**

We operate primarily in North America in the general line container market (74% of our fiscal 2002 net sales) and the coffee can segment of the food container market (12% of our fiscal 2002 net sales). We also provide our customers with metal shearing, coating and printing services through our material center services business (14% of our fiscal 2002 net sales). We have established leading positions in most of our product lines in the United States, other than aerosol cans, in which we have the number three position in the United States. We also manufacture steel ammunition boxes.

The following table sets forth our percentage of net sales for fiscal 2000, 2001 and 2002 for our general line cans, coffee cans and material center services:

	Year E	Year Ended September 30,		
	2000	2001	2002	
<u>Product</u>				
General line cans	75%	76%	74%	
Coffee cans	10	11	12	
Material center services	15	13	14	
Total	100%	100%	100%	

#### General Line Products

The primary uses for our general line cans are for paint and related products, lubricants, roof and driveway sealants, charcoal lighter fluid, and household and personal care products. Specific products include round cans with rings and plugs (typical paint cans), specialty cans (typical PVC or rubber cement cans, brake fluid and other automotive after-market products cans, oblong or F style cans (typically paint thinner cans), and an assortment of other specialty cans), aerosol cans and steel pails. We produce a full line of these products to serve the specific requirements of a diversified base of nationally recognized customers. Most of our products are manufactured in facilities that are strategically located to allow us to deliver product to customer filling locations for such products within a one day transit time.

*Paint Cans.* We produce round paint cans in sizes ranging from one-quarter pint to one gallon, with one-gallon paint cans representing the majority of all paint can sales. Paint cans are manufactured to a variety of performance specifications and may be printed on the outside for customer marketing purposes, although most paint manufacturers use paper labels rather than printed cans.

Specialty Cans. Specialty cans include screw top cans (Monotop<sup>®</sup>), cone top cans, oblong or F style cans and ammunition boxes. Screw top cans (Monotop<sup>®</sup>) typically have an applicator or brush attached to a screw cap and are typically used for PVC pipe cleaner, PVC cement and rubber cement. Cone top cans are typically used for packaging specialty oils and automotive after-market products, including brake fluid, gasoline additives and radiator flushes. Oblong or F style cans are typically used for packaging paint thinners, lacquer thinners, turpentine, deglossers and similar paint-related products, charcoal lighter fluid and waterproofing products. We produce oblong cans in sizes ranging from one pint to one gallon. Oblong cans are generally printed to customer specifications. Ammunition boxes provide a hermetic seal, are coated with a corrosion-resistant finish and are used to package small arms ammunitions and other ordnance products. We sell ammunition boxes to the U.S. Department of Defense as well as to major domestic and foreign producers of ordnance.

*Aerosol Cans*. Aerosol cans are typically used for packaging various household and industrial products, including paint and related products, personal care products, lubricants and insecticides. We produce a variety of sizes, which may be decorated to customer specifications.

*Steel Pails*. Pails are typically used for packaging paint and related products, roof and driveway sealants, marine coatings, vegetable oil, and water repellent. Pails may be either closed head for easy pouring products, or open head for more viscous products, with a lid which is crimped on after filling. The pail market is served by producers of both steel and plastic pails, with steel pails representing an estimated 17% of the pails sold. We manufacture steel pails in sizes ranging from two and one-half to seven gallons. Steel pails are manufactured from either blackplate or cold rolled steel, are typically lined with rust inhibitors or other materials depending on the nature of customers contents and are often printed to customer specifications.

#### Coffee Cans

We produce coffee cans in sizes commonly referred to as one, two and three pound, and various smaller specialty coffee can sizes and shapes. Coffee cans are generally sold to nationally known coffee processing and marketing companies. We do not sell sanitary food cans in which soups, stews, vegetables, pie fillings and other foods are actually cooked in the can. Our coffee cans are also used for packaging edible vegetable oil under government contract for shipment to foreign countries for food relief programs.

#### Material Center Services

We provide material center services (metal shearing, coating and printing services) for our can assembly facilities and for third party customers.

#### Sales and Marketing

We market our products primarily in North America. Sales are made either by our direct sales force or through an agent and distributor network. Our direct sales force is assigned to a territory or to national accounts. The sales force is supported by order entry and scheduling personnel at each plant and by a centralized credit and billing organization. Most of our sales are made by our direct sales force and to distributors for resale. Distributors determine their own prices and assume credit risks. No single distributor represented more than 2% of our net sales in fiscal 2002. Our sales to customers located outside of the United States were less than 3% of our net sales in fiscal 2002.

#### Customers

Our customers include many of the world s leading paint, food, consumer and personal care companies. For fiscal 2002, sales to our 10 largest customers accounted for approximately 45% of our net sales and no single customer accounted for more than 10% of our net sales.

Consistent with industry practice, we enter into multi-year supply agreements with many of our largest customers. However, many of our contracts are requirements contracts under which we supply a percentage of a customer s requirements for our products over a period of time, without any specific commitment to unit volume. In addition, many of our customer contracts, including many of our contracts with our largest customers, provide that the customer may receive competitive proposals for all or a portion of the products we furnish to the customer under the contract. We generally have the rights to retain the customer s business subject to the terms of the competitive proposal.

We believe we have strong relationships with most of our major customers due to: (i) the close proximity of our manufacturing facilities to key customer locations; (ii) our low-cost, flexible manufacturing capabilities; and (iii) our reputation for quality and customer service.

#### **Manufacturing Process**

We generally employ the industry s typical manufacturing process in production of our products, although certain technologies differ from competitors. Following is a sequential list of the specific steps in the can manufacturing process. Not all products require coating and printing.

Process	Description
Shearing	A large coil of tin-coated, blackplate or cold rolled steel is cut into sheets of a specified size depending on the end use of the product.
Coating	A coating is sometimes applied to the side of the sheets which becomes the outside of the containers as a base coat for printing and to the side that becomes the inside of the containers to protect the contents from contact with the steel or tinplate.
Printing	Sheets are decorated with the customer s design. Also known as lithography.
Slitting	Sheets are cut into individual body blanks, which will be formed into cans.
Body-Forming	Body blanks are fed into a body-making machine where they are formed into cylinders or oblong cans and joined at their side seam, by welding or soldering. Handles or nozzles may be attached.
End-Forming	Ends are stamped out of sheets or strips.
Flanging and Seaming	The steel on both ends of the can is rolled to form a flange and the end is attached to the body by folding or seaming.
Testing	The cans are tested for potential leakage.

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Packaging

Cans are stacked onto pallets and shrink-wrapped or packaged in cartons or bags for delivery to customers.

#### **Raw Materials**

Our principal raw materials consist of tinplate, blackplate and cold rolled steel, energy, various coatings, inks and compounds. Steel products represent the largest component of raw material costs. Essentially all of our products are manufactured from tinplate steel, except for pails and ammunition boxes, which are manufactured from either blackplate or cold rolled steel. We purchase all raw materials we require from outside sources.

Various domestic and foreign steel producers supply us with tinplate steel, although we currently purchase most of our tinplate steel from domestic suppliers and countries not currently subject to tariffs imposed by the United States on imports of certain steel products. Procurement from suppliers generally depends on the suppliers product offering, product quality, service and price. As part of our effort to further leverage our purchasing power to obtain favorable raw material prices, we have recently consolidated our steel purchasers among a small group of suppliers, and entered into contractual arrangements with certain suppliers. We have also decreased our purchases of tinplate and cold rolled products from foreign sources, in part due to these tariffs. Because a significant number of reliable suppliers produce the steel used in our process, we believe that we would be able to obtain adequate replacement supplies in the market should one of our current suppliers discontinue supplying us, although the financial terms of these arrangements may differ from our current arrangements. Historically, we have generally been able to increase the price of our products to reflect increases in the price of steel, but we cannot assure you that we will be able to do so in the future.

In addition to steel products, we purchase from various suppliers energy as well as various coatings, inks and compounds used in the manufacturing process. We do not anticipate any future shortages or supply problems for these items based on historical availability and the current number of suppliers. However, we have generally not been successful in the past in passing through price increases in these items to our customers.

#### Competition

The steel container industry is highly competitive and some of our competitors have greater financial resources than we do. Competition is based primarily on price, manufacturing capacity, manufacturing flexibility and quality. We believe that (i) the close proximity of our manufacturing facilities to key customer locations; (ii) our low-cost, flexible manufacturing capabilities and (iii) our reputation for quality and customer service enable us to compete effectively.

In addition, we face competitive risks from substitute products, such as plastics, and, to a lesser extent, composites and flexible packaging containers. During recent years, the steel container industry has experienced slight volume declines in certain product categories due to substitute products. Nonetheless, steel containers are the preferred package in the majority of our customers markets. We believe this is primarily due to: (i) their price stability and competitiveness; (ii) the attractive strength and non-permeable characteristics of steel versus other materials, such as plastics; (iii) their lower storage and handling costs; (iv) their capacity for vacuum or pressure packaging; (v) their ability to hold highly volatile and solvent-based liquids; and (vi) their fire safety characteristics. In addition, we believe steel containers are easier and less costly to recycle and have a higher rate of recycling than alternative materials.

#### Employees

As of September 29, 2002, we employed approximately 1,534 hourly employees and 334 salaried employees. Of the 1,534 hourly employees, 1,048 are non-union and the remaining 486 are covered by seven separate collective bargaining agreements. During the fourth quarter of fiscal 2001, we closed our Elizabeth, New Jersey and Garland, Texas manufacturing facilities and terminated 208 employees. The terminated employees primarily consisted of hourly employees and the terminations were completed by September 30, 2001.

During fiscal 2001, we reached new collective bargaining agreements with three of the seven collective bargaining units covering our employees, which will expire in fiscal 2004. We reached an agreement with Local 14-M of the Graphic Communication Workers International Union at our Trenton, New Jersey facility affecting approximately 76 employees for the period April 1, 2001 through March 31, 2004. We reached an agreement with Chicago Local 458-3M Graphic Communications Workers International Union at our Franklin Park, Illinois facility affecting approximately 15 employees for the period October 1, 2000 through October 15, 2003. We reached an agreement with Local 162 International Association of Machinists and Aerospace Workers Union District 34 at our Cincinnati, Ohio facility affecting approximately 15 employees for the period September 10, 2004. Two of our collective bargaining agreements will expire in fiscal 2003, although both agreements are subject to automatic renewals unless we or the union party to the agreement provides notice otherwise. Our five other collective bargaining agreements will expire in fiscal 2004. While we consider relations with our employees to be good, we cannot assure you that we will be able to negotiate these or other collective bargaining agreements on the same or more favorable terms as the current agreements, or at all and without production interruptions, including labor stoppages. A prolonged labor dispute, which could include a work stoppage, could have a material adverse effect on our business, including our results of operations and financial condition.

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#### **Environmental, Health and Safety Matters**

We are subject to a broad range of federal, state and local environmental, health and safety laws, including those governing discharges to air, soil and water, the handling and disposal of hazardous substances and the investigation and remediation of contamination resulting from the release of hazardous substances. We believe that we are in material compliance with all applicable environmental, health and safety laws, though future expenditures may be necessary in order to maintain such compliance, including compliance with air emission control requirements for volatile organic compounds. In addition, in the course of our operations, we use, store and dispose of hazardous substances. Some of our current and former facilities are currently involved in environmental investigations and remediation obligations that we have identified will have a material adverse effect on our operating results or financial condition, we cannot assure you that no such obligations will arise in the future. Many of our facilities have a history of industrial usage for which investigation and remediation obligations could arise in the future and which could have a material adverse effect on our operating results or financial condition.

In 1999, we entered into a consent order with Owens-Illinois, Inc. and the Georgia Department of Natural Resources to investigate and remediate contamination detected at our Homerville, Georgia facility. Pursuant to the terms of the consent order, we have been conducting removal activities related to certain contaminants released at the facility. Owens- Illinois has been addressing other contaminants released at the facility. We have reached an agreement with Owens-Illinois allocating costs relating to the excavation and removal of buried drums and containers that were discovered at the Homerville facility in December 2001.

In addition, a waste disposal area was uncovered at our Cincinnati, Ohio facility. In early 2002, Ball Corporation, the prior owner of the facility, agreed to address the waste disposal area to the satisfaction of state and county authorities, pursuant to its indemnification obligations to us. While there are certain limitations on Ball s indemnification, we do not believe that we will incur material costs for this issue.

From time to time, we receive requests for information or are identified as potentially responsible parties pursuant to the Federal Comprehensive Environmental Response, Compensation and Liability Act or analogous state laws with respect to off-site waste disposal sites utilized by our current or former facilities or our predecessors in interest. We do not believe that any of these identified matters will have a material adverse effect on our operating results or financial condition.

Reserves for environmental liabilities are recorded when environmental investigation and remediation obligations are probable and related costs are reasonably estimable. We had a reserve of \$386,000 for environmental investigation and remediation obligations as of September 29, 2002; however, there can be no guarantee that future expenditures will not exceed the amount reserved.

#### Item 2. Properties

The following table sets forth certain information with respect to our headquarters and significant manufacturing facilities as of December 19, 2002.

Location	General Character	Approximate Square Footage	Type of Interest
Atlanta, Georgia (Headquarters)	Office	16,000	Leased
Chicago, Illinois (Kilbourn)(Kilbourn)	Manufacturing	141,000	Owned
Cincinnati, Ohio	Manufacturing	467,000	Leased
Dallas, Texas (Thompson)	Held For Sale	110,000	Owned
Dallas, Texas (Southwestern)	Manufacturing	88,000	Owned
Elizabeth, New Jersey	Warehouse /		
	Vacant	211,000	Leased
Fontana, California	Manufacturing	72,000	Leased
Franklin Park, Illinois	Manufacturing	115,000	Leased
Garland, Texas	Warehouse /		
	Vacant	108,000	Leased
Homerville, Georgia	Manufacturing	395,000	Owned
Memphis, Tennessee	Manufacturing /		
	Warehouse	120,000	Leased
Picayune, Mississippi	Manufacturing	60,000	Leased
Trenton, New Jersey	Manufacturing	105,000	Leased
York, Pennsylvania	Manufacturing	97,000	Owned

In June 2001, we implemented a restructuring plan. As part of that plan, redundant equipment at our manufacturing facilities in Elizabeth, New Jersey and Garland, Texas was taken out of service and the facilities were closed in September 2001. We are using approximately 50,000 square feet of the Elizabeth facility and approximately 40,000 square feet of the Garland facility for warehousing finished goods inventory. We are currently marketing the properties for a full or partial sublease. The existing business serviced by those facilities was primarily transferred to our Dallas, Texas and York, Pennsylvania facilities.

In June 2002, we recorded an additional restructuring charge of \$1.2 million related to ongoing lease commitments at our closed Elizabeth, New Jersey manufacturing facility. The charge represents a change in the estimate of net future lease payments included in the original \$21.5 million restructuring charge recorded in the third quarter of fiscal 2001. In June 2001, we anticipated sub-leasing the Elizabeth facility within 12 months. However, due to the weakening of both the general economy and the real estate market, we revised our estimate of facility closure costs to allow additional time to locate a subtenant for this facility.

We believe our properties are generally in good condition, well maintained and suitable for their intended use.

#### Item 3. Legal Proceedings

On October 2, 2002, a civil action was commenced in the Superior Court of Fulton County of the State of Georgia. The plaintiff purports to represent a putative class of our public stockholders (excluding any person or entity related to or affiliated with any of the defendants). Named as defendants in the complaint are we, all members of our board of directors and James Milton (a former director and executive officer). The plaintiff alleges, among other things, that the individual defendants have breached their fiduciary duties of due care and loyalty to our public stockholders and failed to exercise ordinary care and diligence in the exercise of their fiduciary duties by failing to announce an active auction, open bidding or other procedures to increase stockholder value. In addition, the complaint alleges that Mr. Ergas and Mr. Hayford, who have agreed to exchange some of our equity interests for equity interests of BCO Holding, have used inside information for their own benefit and to the detriment of our public stockholders. The complaint seeks injunctive relief, monetary damages, costs and other relief. We believe that this lawsuit is without merit and intend to defend against it vigorously. To that end, in December 2002, all of the defendants filed a motion to prevent the plaintiff from moving forward with discovery in the lawsuit and a motion attacking the sufficiency of the plaintiff s complaint and requesting that it be dismissed.

We are involved in legal proceedings from time to time in the ordinary course of our business. No such currently pending proceedings are expected to have a material adverse effect on us. We are also involved in certain proceedings relating to environmental matters as described under Item 1. Business - Environmental, Health and Safety Matters.

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#### Item 4. Submission of Matters to a Vote of Security Holders

No matters were submitted during the fourth quarter of fiscal 2002 to a vote of our security holders through the solicitation of proxies or otherwise.

#### PART II

#### Item 5. Market for the Registrant s Common Equity and Related Stockholder Matters

BWAY Corporation common stock is traded on the New York Stock Exchange under the ticker symbol BY. There were 53 holders of record of our common stock on December 19, 2002.

Because BWAY is a holding company, our ability to pay dividends is substantially dependent upon the receipt of dividends or other payments from our significant operating subsidiary. In addition, our Credit Facility dated May 22, 2001, as amended (the Credit Facility ), among us, Bankers Trust Company (an affiliate of Deutsche Bank) and various other lenders, restricts our ability to pay dividends or make other restricted payments and places certain restrictions on us with regard to incurring additional indebtedness, other than as specified in the Credit Facility. Additionally, our Indenture dated April 11, 1997 (the Indenture ) relating to our \$100 million, 10<sup>1</sup>/<sub>4</sub>% Senior Subordinated Notes due 2007 (the Senior Subordinated Notes ) also restricts our ability to pay dividends or make other payments, and places certain restrictions on us with regard

to incurring additional indebtedness, other than as specified in the Indenture. In addition, the Merger Agreement prohibits us from paying dividends or incurring additional indebtedness, other than as specified in the Merger Agreement.

Any future determination to pay dividends will be made by our Board of Directors in light of our earnings, financial position, capital requirements, Credit Facility restrictions, Indenture restrictions, Merger Agreement restrictions, business strategies and such other factors as the Board of Directors may deem relevant at such time. Historically, we have not paid any cash distributions or other dividends on our common stock and presently intend to retain our earnings to finance the development of our business for the foreseeable future.

The table below sets forth the high and low sales price information for our common stock for each quarter of fiscal 2001 and fiscal 2002.

Fiscal Quarter	High	Low
First quarter, 2001	\$ 5.31	\$ 2.75
Second quarter, 2001	\$ 4.13	\$ 3.35
Third quarter, 2001	\$ 7.00	\$ 2.60
Fourth quarter, 2001	\$ 7.00	\$ 5.20
First quarter, 2002	\$ 11.75	\$ 6.22
Second quarter, 2002	\$ 13.08	\$ 9.90
Third quarter, 2002	\$ 16.75	\$ 12.25
Fourth quarter, 2002	\$ 16.98	\$ 13.25

#### Item 6. Selected Financial Data

The following table sets forth our selected historical consolidated financial and operating data, which should be read in conjunction with Management s Discussion and Analysis of Financial Condition and Results of Operation included in Item 7 of this report and with our consolidated financial statements and related notes included in Item 8 of this report. The results of operation include the results of the U.S. Can Acquisition described under Business Acquisitions and Dispositions in Item 1 of this report and have been included in our consolidated financial statements from the date of acquisition. The selected consolidated financial and other data as of and for each of the fiscal years in the three-year period ended September 29, 2002 have been derived from our audited financial statements and related notes included in Item 8 of this report. The selected consolidated financial and other data as of and for each of the fiscal years in the two-year period ended October 3, 1999 have been derived from our audited financial statements and related notes which are not included in this report. All amounts are presented in thousands, except ratios.

	Fiscal Year Ended(1)				
	1998	1999	2000	2001	2002
		(D	ollars in thousan	ds)	
Income Statement Data:					
Net sales	\$ 419,474	\$ 487,549	\$ 479,775	\$ 475,039	\$ 527,601
Cost of products sold (excluding depreciation and amortization)	354,973	424,942	422,834	425,084	456,788
Gross profit (excluding depreciation and amortization)	64,501	62,607	56,941	49,955	70,813
Depreciation and amortization(2)	13,465	17,246	22,412	20,713	19,582
Selling and administrative expense	22,748	19,678	17,057	15,610	14,179
Merger related transaction costs(3)					1,478
Restructuring and impairment charge(4)(5)(6)(7)	11,532		5,900	21,500	1,250
Gain on curtailment of postretirement benefits	(1,861)				
Cash flow hedges Effective portion of losses on interest rate contracts reclassified from accumulated other comprehensive loss	2.2	2.7	6.7	7.8	
Net (gains) losses on foreign currency exchange					
contracts not designated as hedging instruments	20.3	77.6	(26.1)	71.8	
The effective portion of net losses on equity contracts i comprehensive income (loss) was \$17.3 million and \$1 September 30, 2010. The effective portion of net gains relationships recorded in other comprehensive income months ended September 30, 2009, respectively, and w	7.3 million fo on interest ra (loss) was \$0	or the three n te contracts i .0 and \$37.8	nonths and ni in designated million for th	ine months en cash flow he ne three mon	nded edging

During the three months and nine months ended September 30, 2010 and 2009, net losses related to ineffectiveness and net losses related to the portion of our risk-management hedging instruments, fair value and cash flow hedges excluded from the assessment of effectiveness were not material.

We expect to reclassify \$12.0 million of pretax net losses on cash flow hedges of the variability in expected future interest payments on floating rate debt from accumulated other comprehensive loss to earnings during the next 12 months.

Fair Value of Financial Instruments

The following tables summarize certain fair value information at September 30, 2010 and December 31, 2009 for assets and liabilities measured at fair value on a recurring basis, as well as the carrying amount and amortized cost of certain other investments:

			Quoted Prices in Active	lue Measuremer	nts Using	
			Markets for Identical	Significant Other Observable	Significant Unobservable	
Description	Carrying Amount	Amortized Cost	Assets (Level 1)	Inputs (Level 2)	Inputs (Level 3)	Fair Value
Sandaria any 20, 2010			(Dollars in	millions)		
September 30, 2010						
Short-term investments Commercial paper Corporate debt securities	\$ 200.0 13.3	\$ 200.0 13.5	\$	\$ 200.0 13.3	\$	\$200.0 13.3
U.S. government and agencies Other securities	17.2 0.8	17.2 0.8	17.2	0.8		17.2 0.8
Total	\$ 231.3	\$ 231.5				
Noncurrent investments Mortgage-backed	\$ 249.2	\$ 286.8	\$	\$ 249.2	\$	\$249.2
U.S. government and agencies	237.8	235.6	237.8		·	237.8
Corporate debt securities Asset-backed Other debt securities	223.7 61.3 6.8	222.0 71.4 9.9		223.7 61.3 3.4	3.4	223.7 61.3 6.8
Marketable equity Equity method and other	402.3	186.0	402.3	<b>J.</b> т	5.7	402.3
investments	159.1	159.1				(1)
Total	\$1,340.2	\$1,170.8				
December 31, 2009						
Short-term investments U.S. government and						
agencies Corporate debt securities Other securities	\$ 18.5 15.8 0.4	\$ 18.8 16.1 0.4	\$ 18.5	\$ 15.8 0.4	\$	\$ 18.5 15.8 0.4
Total	\$ 34.7	\$ 35.3				

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Noncurrent investments						
Mortgage-backed	\$ 240.3	\$ 310.0	\$	\$ 240.3	\$	\$240.3
Corporate debt securities	185.9	195.4		185.9		185.9
U.S. government and						
agencies	81.3	81.7	81.3			81.3
Asset-backed	78.7	94.1		78.7		78.7
Other debt securities	34.4	12.8		3.6	30.8	34.4
Marketable equity	378.7	184.0	378.7			378.7
Equity methods and other						
investments	156.5	156.5				(1)
Total	\$1,155.8	\$1,034.5				
(1) Not applicable						
<sup>(1)</sup> Not applicable		1	7			
		1	1			

	Fair Value Measurements Using				
		Quoted			
		Prices			
		in			
		Active			
		Markets			
		for	Significant	Significant	
		Identical	Other Observable	Unobservable	
	Carrying	Assets (Level	Inputs	Inputs	Fair
Description	Amount	1)	(Level 2)	(Level 3)	Value
Long-term debt, including current portion			(Dollars in millio	ons)	
-					
September 30, 2010	\$(7,137.1)	\$	\$ (7,516.2)	\$	\$(7,516.2)
December 31, 2009	(6,655.0)		(6,827.8)		(6,827.8)
		18			

		Fair V	Fair Value Measurements Using			
		Quoted		8		
		Prices				
		in				
		Active				
		Markets				
		for	Significant	Significant		
		Identical	Other	Unobservable		
	~ ·		Observable	-	- ·	
	Carrying	Assets (Level	Inputs	Inputs	Fair	
Description	Amount	1)	(Level 2)	(Level 3)	Value	
			(Dollars in milli	ons)		
September 30, 2010						
Risk-management instruments						
Interest rate contracts designated as						
hedging instruments						
Sundry	\$487.9	\$	\$ 487.9	\$	\$487.9	
Foreign exchange contracts not						
designated as hedging instruments	12.2		12.2		12.2	
Other receivables	43.2		43.2		43.2	
Other current liabilities	(55.8)		(55.8)		(55.8)	
Equity contracts designed as hedging instruments						
Other current liabilities	(11.4)		(11.4)		(11.4)	
Other noncurrent liabilities	(5.9)		(5.9)		(5.9)	
	(5.7)		(5.7)		(3.7)	
December 31, 2009						
Risk-management instruments						
Interest rate contracts designated as						
hedging instruments						
Sundry	\$134.9	\$	\$ 134.9	\$	\$134.9	
Other noncurrent liabilities	(6.2)		(6.2)		(6.2)	
Foreign exchange contracts not						
designated as hedging instruments	0.0		0.0		0.0	
Other receivables	8.8		8.8		8.8	
Other current liabilities	(10.7)	1-4-14.41	(10.7)	(	(10.7)	
The fair value of the contingent considera				(see note 3), a Lev	lei 3	

measurement in the fair value hierarchy, was \$103.3 million as of September 30, 2010.

We determine fair values based on a market approach using quoted market values, significant other observable inputs for identical or comparable assets or liabilities, or discounted cash flow analyses. The fair value of equity method investments and other investments is not readily available.

Approximately \$560 million of our investments in debt securities, measured at fair value, will mature within five years.

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A summary of the fair value of available-for-sale securities in an unrealized gain or loss position and the amount of unrealized gains and losses (pretax) in other comprehensive income (loss) follows:

	September 30, 2010	December 31, 2009
	(Dollars	s in millions)
Unrealized gross gains	\$230.4	\$ 222.4
Unrealized gross losses	61.2	101.7
Fair value of securities in an unrealized gain position	884.2	579.8
Fair value of securities in an unrealized loss position	322.2	449.4

Other-than-temporary impairment losses on fixed income securities of \$4.7 million and \$11.4 million were recognized in the statement of operations for the three months and nine months ended September 30, 2010, respectively, compared with \$10.7 million and \$18.3 million for the same periods in 2009. These losses primarily relate to credit losses on certain mortgage-backed securities. The amount of credit losses represents the difference between the present value of cash flows expected to be collected on these securities and the amortized cost. Factors considered in assessing the credit loss were the position in the capital structure, vintage and amount of collateral, delinquency rates, current credit support, and geographic concentration.

The securities in an unrealized loss position are composed of fixed-rate debt securities of varying maturities. The value of fixed income securities is sensitive to changes in the yield curve and other market conditions, which led to the decline in value in 2008. Approximately 60 percent of the securities in a loss position are investment-grade debt securities. The majority of these securities first moved into an unrealized loss position during 2008. At this time, there is no indication of default on interest or principal payments for debt securities other than those for which an other-than-temporary impairment charge has been recorded. We do not intend to sell and it is not more likely than not we will be required to sell the securities in a loss position before the market values recover or the underlying cash flows have been received, and we have concluded that no additional other-than-temporary loss is required to be charged to earnings as of September 30, 2010.

Activity related to our available-for-sale investment portfolio was as follows:

	Three Months Ended September 30,			Nine Months Ended September 30,	
	2010	2009	2010	2009	
		(Dollars	s in millions)		
Proceeds from sales	\$59.9	\$426.6	\$427.6	\$1,027.2	
Realized gross gains on sales	7.8	39.5	82.4	56.8	
Realized gross losses on sales	1.6	4.5	3.9	5.5	

Realized gains and losses on sales of available-for-sale securities are computed based upon specific identification of the initial cost adjusted for any other-than-temporary declines in fair value that were recorded in earnings.

In September 2010, we borrowed \$125.0 million of short-term floating-rate debt due in 2011.

Note 7: Stock-Based Compensation

Our stock-based compensation expense consists primarily of performance awards (PAs) and shareholder value awards (SVAs). We recognized pretax stock-based compensation cost of \$46.8 million and \$104.0 million in the third quarter of 2010 and 2009, respectively. In the first nine months of 2010 and 2009, we recognized pretax stock-based compensation expense of \$175.2 million and \$264.4 million, respectively.

PAs are granted to officers and management and are payable in shares of our common stock. The number of PA shares actually issued, if any, varies depending on the achievement of certain earnings per share

targets over a two-year period. PA shares are accounted for at fair value based upon the closing stock price on the date of grant and fully vest at the end of the measurement periods. As of September 30, 2010, the total remaining unrecognized compensation cost related to nonvested PAs amounted to \$66.1 million, which will be amortized over the weighted-average remaining requisite service period of approximately 10 months.

SVAs are granted to officers and management and are payable in shares of common stock at the end of a three-year period. The number of shares actually issued varies depending on our stock price at the end of the three-year vesting period compared to pre-established target prices. We measure the fair value of the SVA unit on the grant date using a Monte Carlo simulation model. The Monte Carlo simulation model utilizes multiple input variables that determine the probability of satisfying the market condition stipulated in the award grant and calculates the fair value of the award. As of September 30, 2010, the total remaining unrecognized compensation cost related to nonvested SVAs amounted to \$57.3 million, which will be amortized over the weighted-average remaining requisite service period of approximately 22 months.

Note 8: Shareholders Equity

As of September 30, 2010, we have purchased \$2.58 billion of our previously announced \$3.0 billion share repurchase program. During the first nine months of 2010, we did not acquire any shares pursuant to this program, nor do we expect any share repurchases under this program for the remainder of 2010.

Note 9: Earnings Per Share

Unless otherwise noted in the footnotes, all per-share amounts are presented on a diluted basis, that is, based on the weighted-average number of outstanding common shares plus the effect of all potentially dilutive common shares (primarily contingently issuable shares and unexercised stock options).

Note 10: Income Taxes

We file income tax returns in the U.S. federal jurisdiction and various state, local, and non-U.S. jurisdictions. We are no longer subject to U.S. federal, state and local, or non-U.S. income tax examinations in major taxing jurisdictions for years before 2005. The IRS began its examination of tax years 2005-2007 during the third quarter of 2008. In the third quarter of 2009, we settled an IRS administrative appeals matter from the 2001-2004 IRS audit. Considering the status of the 2005-2007 IRS examination at that time and the settlement of the IRS administrative appeals matter from the 2001-2004 audit, gross unrecognized tax benefits were reduced approximately \$190 million in the third quarter of 2009. Additionally, in the third quarter of 2009, our income tax expense was reduced by \$54.4 million, and a cash payment of \$52.8 million was paid, after utilization of applicable tax credit carryovers.

The IRS continues its examination of tax years 2005-2007. In the first quarter of 2010, we began the process of advancing the examination procedures to tax years 2008-2009 for certain matters currently being examined in the 2005-2007 audit cycle. Management believes it is reasonably possible that both the 2005-2007 audit and the examination of certain matters for tax years 2008-2009 could conclude within the next 12 months, both of which could cause a significant change in the total amount of unrecognized tax benefits. However, the ultimate resolution of these tax matters is dependent upon a number of factors, including the potential for formal administrative and legal proceedings. As a result, it is not possible to estimate the range of the reasonably possible changes in unrecognized tax benefits that could occur within the next 12 months, nor is it possible to reliably estimate total future cash flows related to these unrecognized tax benefits.

The new U.S. health care legislation (both the primary Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act ) eliminated the tax-free nature of the subsidy we receive for sponsoring retiree drug coverage that is actuarially equivalent to Medicare Part D. This provision is effective January 1, 2013. While this change has a future impact on our net tax deductions related to retiree health benefits, we were required to record a one-time charge to adjust our deferred tax asset for this change in the law in the quarter of enactment. Accordingly, we recorded a non-cash charge of \$85.1 million in the first quarter of 2010.

Note 11: Retirement Benefits

Net pension and retiree health benefit expense included the following components:

	Defined Benefit Pension Plans				
	Three Months Ended September 30,		Nine Months Ended September 30,		
	2010	2009	2010	2009	
	(Dollars in millions)				
Components of net periodic benefit cost					
Service cost	\$ 54.7	\$ 59.3	\$ 165.5	\$ 179.0	
Interest cost	107.9	104.6	323.7	312.0	
Expected return on plan assets	(158.8)	(149.9)	(476.4)	(435.3)	
Amortization of prior service cost	1.7	1.8	5.0	5.4	
Recognized actuarial loss	41.2	21.2	123.5	63.0	
Net periodic benefit cost	\$ 46.7	\$ 37.0	\$ 141.3	\$ 124.1	

	Retiree Health Benefit Plans				
	Three Months Ended September 30,		Nine Months Ended September 30,		
	2010	2009	2010	2009	
	(Dollars in millions)				
Components of net periodic benefit cost					
Service cost	\$ 14.1	\$ 13.4	\$ 42.2	\$ 40.1	
Interest cost	30.3	29.2	90.2	87.7	
Expected return on plan assets	(30.6)	(29.5)	(92.0)	(88.4)	
Amortization of prior service cost	(9.3)	(9.0)	(27.9)	(27.0)	
Recognized actuarial loss	21.3	17.2	63.8	51.5	
Net periodic benefit cost	\$ 25.8	\$ 21.3	\$ 76.3	\$ 63.9	

On a global basis, we have contributed substantially all of the \$100 million required to satisfy minimum funding requirements to our defined benefit pension plans in 2010. In addition, we have contributed \$400.0 million of discretionary funding in the aggregate to several of our global post-retirement benefit plans in 2010. We do not anticipate making any substantial contributions throughout the remainder of the year. Note 12: Contingencies

We are a party to various legal actions, government investigations, and environmental proceedings. The most significant of these are described below. While it is not possible to determine the outcome of these matters, we believe that, except as specifically noted below, the resolution of all such matters will not have

a material adverse effect on our consolidated financial position or liquidity, but could possibly be material to our consolidated results of operations in any one accounting period.

Patent Litigation

We are engaged in the following U.S. patent litigation matters brought pursuant to procedures set out in the Hatch-Waxman Act (the Drug Price Competition and Patent Term Restoration Act of 1984):

Cymbalta: Sixteen generic drug manufacturers have submitted Abbreviated New Drug Applications (ANDAs) seeking permission to market generic versions of Cymbalta prior to the expiration of our relevant U.S. patents (the earliest of which expires in 2013). Of these challengers, all allege non-infringement of the patent claims directed to the commercial formulation, and nine allege invalidity (and some also allege nonenforceability) of the patent claims directed to the active ingredient duloxetine. Of the nine challengers to the compound patent claims, one further alleges invalidity of the claims directed to the use of Cymbalta for treating fibromyalgia. In November 2008 we filed lawsuits in U.S. District Court for the Southern District of Indiana against Actavis Elizabeth LLC; Aurobindo Pharma Ltd.; Cobalt Laboratories, Inc.; Impax Laboratories, Inc.; Lupin Limited; Sandoz Inc.; and Wockhardt Limited, seeking rulings that the compound patent claims are valid, infringed, and enforceable. We filed similar lawsuits in the same court against Sun Pharma Global, Inc. in December 2008 and against Anchen Pharmaceuticals, Inc. in August 2009. The cases have been consolidated and actions against all but Wockhardt Limited have been stayed pursuant to stipulations by the defendants to be bound by the outcome of the litigation through appeal. The Wockhardt Limited trial is scheduled to begin in June 2011. Gemzar® : Mayne Pharma (USA) Inc., now Hospira, Inc. (Hospira); Fresenius Kabi Oncology Plc (Fresenius); Sicor Pharmaceuticals, Inc., now Teva Parenteral Medicines, Inc. (Teva); and Sun Pharmaceutical Industries Inc. (Sun) each submitted one or more ANDAs seeking permission to market generic versions of Gemzar prior to the expiration of our relevant U.S. patents (compound patent expiring in 2010 and method-of-use patent expiring in 2013), and alleging that these patents are invalid. Sandoz Inc. (Sandoz), APP Pharmaceuticals, LLC (APP), Actavis Elizabeth LLC and Actavis Totowa LLC (Actavis), Dr. Reddy s Laboratories, Inc. (Dr. Reddy s), and Accord Healthcare Inc. (Accord) have similarly challenged our method-of-use patent. We filed lawsuits in the U.S. District Court for the Southern District of Indiana against Teva (February 2006), Hospira (October 2006, January 2008, and March 2010), APP (December 2009), Fresenius (February 2010), Actavis (June 2010), Sandoz (August 2010), and Dr. Reddy s (October 2010), and against Accord in the U.S. District Court for the Middle District of North Carolina (October 2010), seeking rulings that our patents are valid and are being infringed. In November 2007, Sun filed a declaratory judgment action in the U.S. District Court for the Eastern District of Michigan, seeking rulings that our method-of-use and compound patents are invalid or unenforceable, or would not be infringed by the sale of Sun s generic product. In August 2009, the district court in Michigan granted a motion by Sun for partial summary judgment, invalidating our method-of-use patent, and the opinion was affirmed by a panel of the Court of Appeals for the Federal Circuit. We are seeking reconsideration of this decision. In March 2010, the district court in Indiana upheld the validity of our compound patent. The court also ruled in our favor on all invalidity theories brought forward by Teva on our method-of-use patent, except for obviousness-type double patenting. The court applied collateral estoppel with regard to this theory, given the ruling in the Sun case. We expect the balance of these cases to follow the final outcomes in the Teva and Sun Cases. Teva s ANDAs have been approved by the FDA, and other generic companies have tentative or final marketing approval for generic generication. Therefore we expect generic gemcitabine to be introduced to the U.S. market as soon as mid-November 2010. Alimta®: Teva Parenteral Medicines, Inc. (Teva); APP; and Barr Laboratories, Inc. (Barr) each submitted ANDAs seeking approval to market generic versions of Alimta prior to the expiration of

the relevant U.S. patent (licensed from the Trustees of Princeton University and expiring in 2016), and alleging the patent is invalid. We, along with Princeton, filed lawsuits in the U.S. District Court for the District of Delaware against Teva, APP, and Barr seeking rulings that the compound patent is valid and infringed. Trial is scheduled for November 2010 against Teva and APP.

Evista®: In 2006, Teva Pharmaceuticals USA, Inc. (Teva) submitted an ANDA seeking permission to market a generic version of Evista prior to the expiration of our relevant U.S. patents (expiring in 2012-2017) and alleging that these patents are invalid, not enforceable, or not infringed. In June 2006, we filed a lawsuit against Teva in the U.S. District Court for the Southern District of Indiana, seeking a ruling that these patents are valid, enforceable, and being infringed by Teva. In September 2009, the court upheld our method-of-use patents (the last expires in 2014) and the court held that our particle-size patents (expiring 2017) are invalid. Both rulings were upheld by the appeals court in September 2010. InvaGen Pharmaceuticals, Inc. (InvaGen) submitted an ANDA in 2008 seeking approval to market a generic version of Evista prior to the expiration of the particle-size patents at issue in the Teva matter. We filed suit against InvaGen in January 2009 in the U.S. District Court for the Southern District of Indiana That action has been stayed pending the outcome of the Teva appeal. Watson Laboratories Inc. (Watson) also submitted an ANDA in March of 2010 seeking approval to market a generic version of Evista prior to the expiration of the particle-size patents at issue in the Teva matter. We filed suit against Watson in May 2010 in the U.S. District Court for the Southern District of Indiana. Strattera®: Actavis Elizabeth LLC (Actavis), Apotex Inc. (Apotex), Aurobindo Pharma Ltd. (Aurobindo), Mylan Pharmaceuticals Inc. (Mylan), Sandoz Inc. (Sandoz), Sun Pharmaceutical Industries Limited (Sun), and Teva Pharmaceuticals USA, Inc. (Teva) each submitted an ANDA seeking permission to market generic versions of Strattera prior to the expiration of our relevant U.S. patent (expiring in 2017), and alleging that this patent is invalid. In 2007, we brought a lawsuit against Actavis, Apotex, Aurobindo, Mylan, Sandoz, Sun, and Teva in the United States District Court for the District of New Jersey. In August 2010, the court ruled that our patent is invalid. Several companies have received final approval to market generic atomoxetine, but the Court of Appeals for the Federal Circuit granted an injunction prohibiting the launch of generic atomoxetine until the court renders an opinion. The appeal is scheduled to be heard by the court in December 2010. Zydus Pharmaceuticals (Zydus) filed an action in the New Jersey district court in October 2010 seeking a declaratory judgment that it has the right to launch a generic atomoxetine product, based on the district court ruling. We believe that Zydus is subject to the injunction issued by the court of appeals, and we are considering our legal options.

We believe each of these Hatch-Waxman challenges is without merit and expect to prevail in this litigation. However, it is not possible to determine the outcome of this litigation, and accordingly, we can provide no assurance that we will prevail. An unfavorable outcome in any of these cases could have a material adverse impact on our future consolidated results of operations, liquidity, and financial position.

We have received challenges to Zyprexa patents in a number of countries outside the U.S.:

In Canada, several generic pharmaceutical manufacturers have challenged the validity of our Zyprexa patent (expiring in 2011). In April 2007, the Canadian Federal Court ruled against the first challenger, Apotex Inc. (Apotex), and that ruling was affirmed on appeal in February 2008. In June 2007, the Canadian Federal Court held that an invalidity allegation of a second challenger, Novopharm Ltd. (Novopharm), was justified and denied our request that Novopharm be prohibited from receiving marketing approval for generic olanzapine in Canada. Novopharm began selling generic olanzapine in Canada in the third quarter of 2007. In September 2009, the Canadian Federal Court ruled against us in the Novapharm suit, finding our patent invalid. However, in July 2010 the appeals court set aside the decision and remitted the limited issues of utility and sufficiency of disclosure to the trial court.

In Germany, the German Federal Supreme Court upheld the validity of our Zyprexa patent (expiring in 2011) in December 2008, reversing an earlier decision of the Federal Patent Court. Following the

decision of the Supreme Court, the generic companies who launched generic olanzapine based on the earlier decision either agreed to withdraw from the market or were subject to injunction. We have negotiated settlements of the damages arising from infringement with most of the generic companies. We have received challenges in a number of other countries, including Spain, Austria, Australia, Portugal, and several smaller European countries. In Spain, we have been successful at both the trial and appellate court levels in defeating the generic manufacturers challenges, but additional actions against multiple generic companies are now pending. In March 2010, the District Court of Hague ruled against us and revoked our compound patent in the Netherlands. We have appealed this decision. We have also successfully defended Zyprexa patents in Austria and Portugal.

We are vigorously contesting the various legal challenges to our Zyprexa patents on a country-by-country basis. We cannot determine the outcome of this litigation. The availability of generic olanzapine in additional markets could have a material adverse impact on our consolidated results of operations.

Zyprexa Litigation

We have been named as a defendant in a large number of Zyprexa product liability lawsuits in the U.S. and have been notified of many other claims of individuals who have not filed suit. The lawsuits and unfiled claims (together the

claims ) allege a variety of injuries from the use of Zyprexa, with the majority alleging that the product caused or contributed to diabetes or high blood-glucose levels. The claims seek substantial compensatory and punitive damages and typically accuse us of inadequately testing for and warning about side effects of Zyprexa. Many of the claims also allege that we improperly promoted the drug. Almost all of the federal lawsuits are part of a Multi-District Litigation (MDL) proceeding before The Honorable Jack Weinstein in the Federal District Court for the Eastern District of New York (EDNY) (MDL No. 1596).

Since June 2005, we have entered into agreements with various claimants attorneys involved in U.S. Zyprexa product liability litigation to settle a substantial majority of the claims. The agreements cover a total of approximately 32,690 claimants, including a large number of previously filed lawsuits and other asserted claims. The two primary settlements were as follows:

In 2005, we settled and paid more than 8,000 claims for \$690.0 million, plus \$10.0 million to cover administration of the settlement.

In 2007, we settled and paid more than 18,000 claims for approximately \$500 million. We are prepared to continue our vigorous defense of Zyprexa in all remaining claims. The U.S. Zyprexa product liability claims not subject to these agreements include approximately 100 lawsuits in the U.S. covering approximately 185 plaintiffs, of which about 75 lawsuits covering about 80 plaintiffs are part of the MDL. The MDL cases have been scheduled for trial in groups, the earliest trial groups have been tentatively scheduled for December 2010. We also have trials scheduled in California in February 2011 and in Texas state court in August 2011. In January 2009, we reached resolution with the Office of the U.S. Attorney for the Eastern District of Pennsylvania (EDPA), and the State Medicaid Fraud Control Units of 36 states and the District of Columbia, of an investigation related to our U.S. marketing and promotional practices with respect to Zyprexa. As part of the resolution, we pled guilty to one misdemeanor violation of the Food, Drug, and Cosmetic Act for the off-label promotion of Zyprexa in elderly populations as treatment for dementia, including Alzheimer s dementia, between September 1999 and March 2001. We recorded a charge of \$1.42 billion for this matter in the third quarter of 2008. In 2009, we paid substantially all of this amount, as required by

the settlement agreements. As part of the settlement, we have entered into a corporate integrity agreement with the Office of Inspector General (OIG) of the U.S. Department of Health and Human Services (HHS), which requires us to maintain our compliance program and to undertake a set of defined corporate integrity obligations for five years. The agreement also provides for an independent third-party review organization to assess and report on the company s systems, processes, policies, procedures, and practices.

In October 2008, we reached a settlement with 32 states and the District of Columbia related to a multistate investigation brought under various state consumer protection laws. While there is no finding that we have violated any provision of the state laws under which the investigations were conducted, we accrued \$62.0 million and agreed to undertake certain commitments regarding Zyprexa for a period of six years, through consent decrees filed with the settling states.

We have been served with lawsuits filed by the states of Alaska, Arkansas, Connecticut, Idaho, Louisiana, Minnesota, Mississippi, Montana, New Mexico, Pennsylvania, South Carolina, Utah, and West Virginia alleging that Zyprexa caused or contributed to diabetes or high blood-glucose levels, and that we improperly promoted the drug. These suits seek to recover the costs paid for Zyprexa through Medicaid and other drug-benefit programs, as well as the costs alleged to have been incurred and that will be incurred by the states to treat Zyprexa-related illnesses. The Alaska case was settled in March 2008 for a payment of \$15.0 million, plus terms designed to ensure, subject to certain limitations and conditions, that Alaska is treated as favorably as certain other states that may settle with us in the future over similar claims. We have reached agreements to settle the Zyprexa-related claims of all of these states except Minnesota, with which we are in advanced discussions. In the second and third quarters of 2009, we incurred pretax charges of \$105.0 million and \$125.0 million, respectively, reflecting the then-current probable and estimable exposures in connection with these claims.

In 2005, two lawsuits were filed in the EDNY purporting to be nationwide class actions on behalf of all consumers and third-party payors, excluding governmental entities, which have made or will make payments for their members or insured patients being prescribed Zyprexa. These actions have now been consolidated into a single lawsuit, which is brought under certain state consumer protection statutes, the federal civil RICO statute, and common law theories, seeking a refund of the cost of Zyprexa, treble damages, punitive damages, and attorneys fees. Two additional lawsuits were filed in the EDNY in 2006 on similar grounds. As with the product liability suits, these lawsuits allege that we inadequately tested for and warned about side effects of Zyprexa and improperly promoted the drug. In September 2008, Judge Weinstein certified a class consisting of third-party payors, excluding governmental entities and individual consumers. We appealed the certification order and Judge Weinstein s order denying our motion for summary judgment in September 2008. In September 2010, both decisions were reversed by the Second Circuit Court of Appeals, which found that the case cannot proceed as a class action and entered a judgment in our favor on plaintiffs overpricing claim. Plaintiffs are seeking a reconsideration of this decision.

We cannot determine with certainty the additional number of lawsuits and claims that may be asserted. The ultimate resolution of Zyprexa product liability and related litigation could have a material adverse impact on our consolidated results of operations, liquidity, and financial position.

# Other Product Liability Litigation

We have been named as a defendant in numerous other product liability lawsuits involving primarily diethylstilbestrol (DES), thimerosal, and Byetta. Approximately half of these claims are covered by insurance, subject to deductibles and coverage limits.

Product Liability Insurance

Because of the nature of pharmaceutical products, it is possible that we could become subject to large numbers of product liability and related claims for other products in the future. In the past several years, we have been unable to obtain product liability insurance due to a very restrictive insurance market. Therefore, for substantially all of our currently marketed products, we have been and expect that we will continue to be completely self-insured for future product liability losses. In addition, there is no assurance that we will be able to fully collect from our insurance carriers in the future.

**Environmental Matters** 

Under the Comprehensive Environmental Response, Compensation, and Liability Act, commonly known as Superfund, we have been designated as one of several potentially responsible parties with respect to fewer than 10 sites. Under Superfund, each responsible party may be jointly and severally liable for the entire amount of the cleanup. We also continue remediation of certain of our own sites. We have accrued for estimated Superfund cleanup costs, remediation, and certain other environmental matters. This takes into account, as applicable, available information regarding site conditions, potential cleanup methods, estimated costs, and the extent to which other parties can be expected to contribute to payment of those costs. We have limited liability insurance coverage for certain environmental liabilities.

Note 13: Other - Net, Expense (Income)

Other - net, expense (income) comprised the following:

	Three Months Ended September 30,		Nine Months Ended September 30,		
	2010	2009	2010	2009	
	(Dollars in millions)				
Interest expense	\$ 47.2	\$ 59.2	\$ 142.3	\$ 211.1	
Interest income	(16.3)	(15.2)	(37.9)	(61.4)	
Other	(9.2)	22.9	(138.8)	12.0	
Other - net, expense (income)	\$ 21.7	\$ 66.9	\$ (34.4)	\$ 161.7	

Other Income for the first nine months of 2010 is primarily related to damages recovered from generic pharmaceutical companies following Zyprexa patent litigation in Germany and a gain related to the disposition of investment securities.

Item 2. Management s Discussion and Analysis of Financial Condition and Results of Operations OPERATING RESULTS

Executive Overview

# I. Financial Results

Our worldwide revenue increased 2 percent and 6 percent to \$5.65 billion and \$16.89 billion for the third quarter and first nine months of 2010, respectively, driven primarily by the increase in revenue related to the collective growth of Alimta, Humulin®, Cymbalta, and animal health products for the third quarter and, in addition for the first nine months of 2010, Zyprexa, Cialis® and Humalog®. Net income for the third quarter and the first nine months of 2010 increased 38 percent and 14 percent, to \$1.30 billion and \$3.90 billion, respectively, compared with the same periods of 2009. Earnings per share for the third-quarter and the first nine months of 2010 increased 37 percent and 14 percent to \$1.18 per share and \$3.53 per share, respectively, compared with the same periods of 2009. Net income

for the third quarter and first nine months of 2010 and 2009 was affected by the following highlighted items: 2010

Due to the enactment of health care reform in the U.S. in March 2010, total revenue decreased by approximately \$25 million (pretax), or \$.02 per share, in the third quarter, and approximately \$155 million (pretax), or \$.11 per share, in the first nine months of 2010, as a result of higher rebates. We also recorded a one-time non-cash deferred income tax charge in the first quarter of \$85.1 million, or \$.08 per share, associated with the imposition of tax on the prescription drug subsidy of our U.S. retiree health plan.

We recognized asset impairments, restructuring, and other special charges of \$59.5 million (pretax), or \$.03 per share, in the third quarter, and \$113.0 million (pretax), or \$.07 per share, for the first nine months of 2010, respectively, primarily related to our previously announced initiatives to reduce our cost structure and global workforce as well as previously announced strategic decisions.

We incurred acquired IPR&D charges associated with the in-licensing arrangement with Acrux Limited of \$50.0 million (pretax), which decreased earnings per share by \$.03 in the first quarter.

#### 2009

We recognized asset impairments, restructuring, and other special charges of \$424.8 million (pretax), which decreased earnings per share by \$.26 in the third quarter for asset impairments and restructuring primarily related to the sale of our Tippecanoe manufacturing site to an affiliate of Evonik Industries AG. We incurred pretax charges of \$105.0 million, or \$.06 per share, in the second quarter, and \$125.0 million, or \$.07 per share, in the third quarter, representing the currently probable and estimable exposures in connection with the claims of several states that did not participate in the EDPA settlement related to Zyprexa.

II. Late-Stage Pipeline

Our long-term success depends, to a great extent, on our ability to continue to discover and develop innovative pharmaceutical products and acquire or collaborate on compounds currently in development by other biotechnology or pharmaceutical companies. We currently have nearly 70 potential new drugs in human testing and a larger number of projects in earlier stages of development.

Our new molecular entities currently in Phase III clinical trial testing include the following:

Enzastaurin A small molecule for the treatment of diffuse large B-cell lymphoma

GLP-1 Fc A glucagon-like peptide 1 analog for the treatment of type 2 diabetes

**Necitumumab** A fully human monoclonal antibody being investigated as a treatment for non-small cell lung cancer **NERI IV** A potent and highly selective norepinepherine reuptake inhibitor being investigated as a treatment for major depression and attention-deficit hyperactivity disorder.

Ramucirumab A monoclonal antibody being investigated as a treatment metastatic for breast and gastric cancersSolanezumab An amyloid beta (AB) antibody for the treatment of Alzheimer s disease

Tasisulam A small-molecule compound for the treatment of melanoma

Our new molecular entities that have been submitted for regulatory review include the following:

Arxxant A potential treatment for diabetic retinopathy

**Axiron** A testosterone solution to be applied via an underarm applicator, a potential treatment for testosterone deficiency

Liprotamase A non-porcine pancreatic enzyme replacement therapy

The following are presented to provide updates on our late-stage pipeline developments that have occurred this year: Third Quarter

We and our partner, MacroGenics, Inc., announced that an independent Data Monitoring Committee (DMC) completed a planned analysis of one-year safety and efficacy data of the Protégé Phase 3 clinical trial of teplizumab, an investigational biologic under development for the treatment of individuals with recent-onset type 1 diabetes. The DMC concluded that the primary efficacy endpoint of the study was not met. The DMC, noting that all administration of experimental drug had been completed, commented that appropriate safety monitoring is warranted. No unanticipated safety issues were identified in the DMC s review. The companies have decided to suspend further enrollment and dosing of patients in two other ongoing clinical trials of teplizumab in type 1 diabetes. In October 2010 we notified MacroGenics of our intent to terminate our collaboration agreement for the development of teplizumab. We are evaluating the financial impact of halting the development of teplizumab.

The FDA issued a complete response letter regarding the NDA for Bydureon. In the complete response letter, the FDA requested a safety study to measure the potential for heart rhythm disturbances when exenatide is used at higher than average doses. Additionally, the FDA has now requested the results of the already completed DURATION-5 study to evaluate the efficacy, and the labeling of the safety and effectiveness, of the commercial formulation of Bydureon. We, along with our partners Amylin Pharmaceuticals, Inc. and Alkermes, Inc., have set a goal to submit our reply to the complete response letter by the end of 2011, pending discussions with the FDA. Based on the requirements for additional data, this will likely be considered a Class 2 resubmission requiring a six-month review.

We completed our acquisition of Alnara Pharmaceuticals, Inc., a privately-held company developing protein therapeutics for the treatment of metabolic diseases. Alnara s lead product in development is liprotamase, a non-porcine pancreatic enzyme replacement therapy. Liprotamase is under review by the FDA for the treatment of exocrine pancreatic insufficiency.

We halted development of semagacestat, a gamma secretase inhibitor being studied as a potential treatment for Alzheimer s disease, because preliminary results from two ongoing long-term Phase III studies showed the compound did not slow disease progression and was associated with worsening of clinical measures of cognition and the ability to perform activities of daily living.

The FDA Anesthetic and Life Support Drugs Advisory Committee voted 8-6 in favor of expanding the pain indications for Cymbalta to a broader population that will be further defined by the FDA, if approved.

# Second Quarter

We, along with our partner, Kowa Pharmaceuticals America Inc., announced the U.S. launch of Livalo<sup>®</sup>. In addition to a proper diet, Livalo is used for the treatment of high cholesterol (primary hyperlipidemia or mixed dyslipidemia) in adults.

First Quarter

We entered into an exclusive worldwide license agreement for the potential commercialization of Acrux s experimental testosterone solution (proposed tradename Axiron). The New Drug Application for Axiron is currently under regulatory review by the FDA for the treatment of testosterone deficiency (hypogonadism) in men.

We, along with our partners Amylin and Alkermes, Inc., submitted Bydureon for review by the European Medicines Agency.

III. Legal, Regulatory, and Other Matters

In September 2009, we set a goal to reduce our expected cost structure by \$1 billion by the end of 2011. This savings will come from a series of actions, including reducing a targeted 5,500 positions by the end of 2011 (excluding strategic additions in high-growth emerging markets and Japan, as well as additions for acquisitions), outsourcing activities, and consolidating certain activities to become more efficient. We expect the majority of the savings to occur in the marketing, selling, and administrative line item in the consolidated statement of operations, and to a lesser extent, cost of sales and research and development.

The U.S. District Court for the Southern District of Indiana has upheld our compound patent for Gemzar (exclusivity based on this patent expires on November 15, 2010). The U.S. District Court for the Eastern District of Michigan granted a motion for partial summary judgment in August 2009, invalidating our U.S. method-of-use patent for Gemzar (expiring in 2013) and on July 28, 2010, the Court of Appeals for the Federal Circuit affirmed that decision. We have asked for reconsideration of this decision by the Federal Circuit court. Nevertheless, some of the generic companies have tentative or final marketing approval for generic gemcitabine, and therefore we expect generic gemcitabine to be introduced to the U.S. market as soon as mid-November 2010, following the expiration of the compound patent.

The U.S. District Court for the District of New Jersey ruled that the method-of-use patent for Strattera, which expires in 2017, is invalid. We are currently appealing this decision to the U.S. Court of Appeals for the Federal Circuit, and a hearing is scheduled in December 2010. The Appeals Court has granted an injunction that prevents the launch of generic atomoxetine until a ruling is rendered. Several generic companies have tentative approval to market generic atomoxetine.

The enactment of the Patient Protection and Affordable Care Act and The Health Care and Education Reconciliation Act of 2010 in March 2010 brings significant changes to U.S. health care. These changes began to affect our financial results in the first quarter of 2010 and will continue to have significant impact on our results in the future. Changes to the rebates for prescription drugs sold to Medicaid beneficiaries, which increase the minimum statutory rebate for branded drugs from 15.1 percent to 23.1 percent, were generally effective in the first quarter of 2010. This rebate has been expanded to managed-Medicaid, a program that provides for the delivery of Medicaid benefits via managed care organizations, under arrangements between those organizations and state Medicaid agencies. Additionally, a prescription drug discount program for outpatient drugs in certain types of health care facilities that serve low-income and uninsured patients (known as 340B facilities) has been expanded. Also, there are changes to the tax treatment of subsidies paid by the government to employers, such as us, who provide their retirees with a drug benefit at least equivalent to the Medicare Part D drug benefit. Beginning in 2013, the federal government will tax the subsidy it provides to such employers. While this tax will not take effect for three more years, accounting rules dictate that we adjust our deferred tax asset through a one-time non-cash charge upon enactment of the tax law change, which we recorded in the first quarter of 2010. In addition, the federal government created an expedited regulatory approval pathway for biosimilars or follow-on biologics (copies of biological compounds) in the U.S. Biologics will have up to 12.5 years of data-package protection following launch.

Beginning in 2011, drug manufacturers will provide a discount of 50 percent of the cost of branded prescription drugs for Medicare Part D participants who are in the doughnut hole (the coverage gap in

Medicare prescription drug coverage). The doughnut hole will be phased out by the federal government between 2011 and 2020. Additionally, beginning in 2011, a nondeductible annual fee will be imposed on pharmaceutical manufacturers and importers that sell branded prescription drugs to specified government programs. This fee is allocated to companies based on their prior calendar year market share for branded prescription drug sales into these government programs. Regulations have not been drafted to implement the various elements of this legislation. A guidance project is currently underway within the IRS and U.S. Treasury concerning the implementation of this nondeductible annual fee. However, guidance has not yet been publicly released to implement the pharmaceutical fee legislation.

In its budget submission to Congress in February 2010, the Obama administration proposed changes to the manner in which the U.S. would tax the international income of U.S.-based companies. Some provisions changing taxation of international income were enacted in August, 2010, which did not have a material effect on results of operations. While it is uncertain how the U.S. Congress may address U.S. tax policy matters in the future, reform of U.S. taxation, including taxation of international income, continues to be a topic of discussion for Congress. A significant change to the U.S. tax system, including changes to the taxation of international income, could have a material adverse effect on our consolidated results of operations. On October 25, 2010, Puerto Rico enacted income and excise tax legislation affecting to our Puerto Rican operations which will become effective on January 1, 2011. We are currently evaluating the impact on our consolidated results of operations in future years.

Certain other federal and state health care proposals may continue to be debated, and could place downward pressure on pharmaceutical industry sales or prices. These proposals include legalizing the importation of prescription drugs and other cost-control strategies. We expect pricing pressures at state levels to become more severe, which could have a material adverse effect on our consolidated results of operations.

International operations also are generally subject to extensive price and market regulations, and several European countries have recently required either price decreases or rebate increases in response to economic pressures. There are proposals for cost-containment measures pending in a number of additional countries, including proposals that would directly or indirectly impose additional price controls, limit access to or reimbursement for our products, or reduce the value of our intellectual property protection. These proposals are expected to increase in both frequency and impact, given the effect of the downturn in the global economy on local governments. Revenue

Revenue for the third quarter and the first nine months of 2010 increased 2 percent and 6 percent to \$5.65 billion and \$16.89 billion, respectively, driven primarily by the increase in revenue related to the collective growth of Alimta, Humulin, Cymbalta, and animal health products for the third quarter and, in addition for the first nine months of 2010, Zyprexa, Cialis and Humalog. Revenue in the U.S. of \$3.15 billion remained essentially flat for the third quarter and increased \$413.0 million, or 5 percent during the first nine months of 2010, compared with the same periods of 2009 due to higher prices and, to a lesser extent, increased volume, offset in part by approximately \$25 million and approximately \$155 million in the third quarter and first nine months of 2010, respectively, in higher rebates resulting from U.S. health care reform. Third-quarter 2010 total revenue would have been reduced by approximately \$25 million, due primarily to the issuance of government guidance that clarified the implementation of certain aspects of health care reform legislation, resulting in a reduction of a prior accrual.

Revenue outside the U.S. increased \$88.4 million, or 4 percent, and \$574.3 million, or 8 percent, for the third quarter and first nine months of 2010, respectively, compared with the same periods of 2009 due to increased demand and, to a lesser extent for the first nine months of 2010, the positive impact of

foreign exchange rates, partially offset by lower prices and, for the third quarter, by the negative impact of foreign exchange rates. For the third quarter, the worldwide revenue increase was comprised of an increase of 3 percent due to higher prices, offset by a 1 percent decrease due to the impact of foreign exchange rates, while volume remained essentially flat. For the first nine months of 2010, worldwide sales volume increased 3 percent; selling prices increased 2 percent; and the favorable impact of foreign exchange rates contributed 1 percent of revenue growth. The following tables summarize our revenue activity for the three- and nine-month periods ended September 30, 2010 and 2009:

	Three Months Ended			Three Months Ended September	
		September 30, 20	10	30,	Percent
		Outside		2009	Change from
Product	U.S. <sup>1</sup>	U.S. <sup>2</sup>	Total <sup>2</sup>	Total	2009
		(De	ollars in millions)	)	
Zyprexa	\$ 604.6	\$ 608.2	\$ 1,212.7	\$ 1,223.0	(1)
Cymbalta	643.2	162.8	806.1	790.2	2
Alimta	245.5	314.8	560.3	461.9	21
Humalog	288.9	205.1	494.0	500.2	(1)
Cialis	153.5	253.0	406.5	397.2	2
Animal health products	197.8	155.5	353.3	314.6	12
Gemzar	219.7	104.9	324.6	331.8	(2)
Humulin	120.7	157.3	278.0	260.4	7
Evista	166.4	90.4	256.8	259.5	(1)
Forteo®	118.7	81.0	199.7	213.1	(6)
Strattera	85.1	42.8	127.9	145.5	(12)
Other pharmaceutical products	190.9	275.9	466.9	488.1	(4)
Total net product sales	3,035.0	2,451.7	5,486.8	5,385.5	2
Collaboration and other revenue <sup>3</sup>	115.4	52.6	168.0	176.5	(5)
Total revenue	\$ 3,150.4	\$ 2,504.4	\$ 5,654.8	\$ 5,562.0	2
		32			

		Nine Months Endec September 30, 2010 Outside		Nine Months Ended September 30, 2009	Percent Change
Product	<b>U.S</b> . <sup>1</sup>	U.S.	Total <sup>2</sup>	Total	from 2009
		(Do)	llars in millions)		
Zyprexa	\$ 1,826.2	\$ 1,864.4	\$ 3,690.6	\$ 3,549.2	4
Cymbalta	2,001.8	475.2	2,477.0	2,243.9	10
Alimta	721.8	917.7	1,639.5	1,182.5	39
Humalog	898.4	606.6	1,505.1	1,428.2	5
Cialis	468.6	764.9	1,233.5	1,119.6	10
Animal health products	540.5	426.5	967.1	854.0	13
Gemzar	583.1	322.6	905.8	1,052.8	(14)
Humulin	350.5	450.5	801.0	749.1	7
Evista	500.2	257.7	757.9	767.7	(1)
Forteo	367.0	236.8	603.8	603.9	
Strattera	288.4	133.0	421.3	447.2	(6)
Other pharmaceutical products	536.8	869.4	1,406.0	1,392.5	1
Total net product sales	9,083.3	7,325.3	16,408.6	15,390.6	7
Collaboration and other revenue <sup>3</sup>	362.6	117.8	480.4	511.2	(6)
Total revenue	\$ 9,445.9	\$ 7,443.1	\$ 16,889.0	\$ 15,901.8	6
<sup>1</sup> U.S. revenue					
includes					
revenue in					
Puerto Rico.					
<sup>2</sup> Numbers may					
not add due to					
rounding.					
<sup>3</sup> Collaboration					
and other					
revenue is					
primarily					
composed of					
Erbitux royalties					
and 50 percent					
of Byetta s gross					
margin in the U.S.					
Product Highlights					

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Zyprexa, our top-selling product, is a treatment for schizophrenia, acute mixed or manic episodes associated with bipolar I disorder, and bipolar maintenance. In the third quarter and first nine months of 2010, Zyprexa sales in the U.S. increased 6 percent and 8 percent, respectively, compared with the same periods of 2009, driven by higher prices, partially offset by the impact of wholesaler buying patterns. Sales outside the U.S. decreased 7 percent and remained essentially flat for the third quarter and first nine months of 2010, respectively, with the third quarter decrease driven by the unfavorable impact of foreign exchange rates and lower prices. The results in the first nine months of 2010 were driven by the favorable impact of foreign exchange rates offset by lower prices. We will lose effective exclusivity for Zyprexa in the U.S. in October 2011. We will also lose effective exclusivity in most of Europe in 2011. In the five major European countries, which in the aggregate have approximately \$850 million of sales for the first nine months of 2010, we will lose effective exclusivity in April 2011 (Spain) and September 2011 (France, Germany, Italy, and the United Kingdom). As a result, we expect generic olanzapine to be introduced to the market following the expiration of these patents. While it is difficult to predict the precise impact on Zyprexa sales, the introduction of generics will result in a rapid and severe decline in our Zyprexa sales which will have a material adverse effect on results of operations and cash flows. In Japan, our second-largest market for Zyprexa, with over \$300 million of sales for the first nine months of 2010, our patent expires in December 2015.

U.S. sales of Cymbalta, a product for the treatment of major depressive disorder, diabetic peripheral neuropathic pain, generalized anxiety disorder, and fibromyalgia, decreased 1 percent for the third quarter and increased 7 percent during the first nine months of 2010, with the third quarter decrease driven primarily by the impact of wholesaler buying patterns, partially offset by higher prices. The increase in the first nine months of 2010 was due primarily to higher prices. Sales outside the U.S. increased 18 percent and 27 percent during the third quarter and first nine months of 2010, respectively, compared with the same periods in 2009, driven primarily by increased demand resulting from recent launches in Japan and Canada.

U.S. sales of Alimta, a treatment for various cancers, increased 14 percent and 23 percent during the third quarter and first nine months of 2010, respectively, due to increased demand and higher prices. Sales outside the U.S. increased 28 percent and 54 percent for the same periods, due to increased demand. Demand outside the U.S. was favorably impacted by the continued strong growth of the non-small cell lung cancer indication in Japan.

U.S. sales of Humalog, our injectable human insulin analog for the treatment of diabetes, decreased 7 percent for the third quarter and increased 1 percent during first nine months of 2010, respectively, with the third quarter decrease driven in part by the impact of wholesaler buying patterns. The increase for the first nine months of 2010 was due to higher prices. Sales outside the U.S. increased 8 percent and 12 percent for the third quarter and first nine months of 2010, respectively, driven by increased demand and higher prices, offset partially in the third quarter by the unfavorable impact of foreign exchange rates.

U.S. sales of Cialis, a treatment for erectile dysfunction, decreased 3 percent for the third quarter and increased 2 percent during the first nine months of 2010, with the third quarter decrease driven primarily by the impact of wholesaler buying patterns, partially offset by higher prices. The increase for the first nine months of 2010 was due to higher prices. Sales outside the U.S. increased 6 percent and 15 percent for the same periods, with the third quarter increase driven by increased demand and higher prices, offset partially by the unfavorable impact of foreign exchange rates. The increase for the first nine months was due to increased demand and, to a lesser extent, the favorable impact of foreign exchange rates.

U.S. sales of Gemzar, a product approved to treat various cancers, increased 15 percent and 5 percent during the third quarter and first nine months of 2010, respectively, with the increase due to higher prices and the favorable impact of wholesaler buying patterns. Sales outside the U.S. decreased 25 percent and 35 percent for the third quarter and first nine months of 2010, respectively, due to lower demand and lower prices as a result of the entry of generic competition in most major markets other than Japan. The U.S. Gemzar method-of-use patent has been held invalid by the Court of Appeals for the Federal Circuit, and various generic manufacturers have tentative or final FDA approval to market generic gemcitabine. Therefore, we expect generic gemcitabine to be introduced to the U.S. market as soon as mid-November 2010, following the expiration of the compound patent on November 15, 2010. While it is difficult to predict the precise impact on Gemzar sales, the introduction of generics would result in a rapid and severe decline in our U.S. Gemzar sales.

U.S. sales of Humulin, an injectable human insulin for the treatment of diabetes, increased 14 percent and 17 percent during the third quarter and first nine months of 2010, respectively, driven by increased volume resulting from the new partnership with Walmart for Humulin ReliOn® and, to a lesser extent, higher prices. Sales outside the U.S. increased 2 percent and remained essentially flat for the third quarter and first nine months of 2010, respectively, with the third quarter results driven by increased demand, partially offset by lower prices and the unfavorable impact of foreign exchange rates. The favorable impact of foreign exchange rates and higher demand for the first nine months of 2010 was offset by lower prices.

U.S. sales of Evista, a product for the prevention and treatment of osteoporosis in postmenopausal women and for reduction of risk of invasive breast cancer in postmenopausal women with osteoporosis and postmenopausal women at high risk for invasive breast cancer, decreased 5 percent and 1 percent during the third quarter and first nine months of 2010, respectively, due to lower demand, partially offset by higher prices. Sales outside the U.S. increased 6 percent for the third quarter and decreased 1 percent for the first nine months of 2010, respectively, with third quarter increases driven primarily by increased demand. The decrease during the first nine months of 2010 was due to lower demand and, to a lesser extent, lower prices, partially offset by the favorable impact of foreign exchange rates. U.S. sales of Forteo, an injectable treatment for osteoporosis in postmenopausal women and men at high risk for fracture, decreased 12 percent and 6 percent during the third quarter and first nine months of 2010, respectively, driven primarily by lower demand, partially offset by higher prices. Sales outside the U.S. increased 4 percent and 10 percent for the third quarter and first nine months of 2010, respectively, with the increase in the third quarter due to higher prices and, to a lesser extent, increased demand, partially offset by the unfavorable impact of foreign exchange rates.

U.S. sales of Strattera, a treatment of attention-deficit hyperactivity disorder in children, adolescents, and adults, decreased 20 percent and 12 percent during the third quarter and first nine months of 2010, respectively, due primarily to lower demand, and to a lesser extent, lower net effective selling prices. Sales outside the U.S. increased 11 percent and 12 percent for the third quarter and first nine months of 2010, respectively, with the increase for the third quarter driven by increased demand, partially offset by lower prices. Demand outside the U.S. was favorably impacted by continued strong demand in Japan. The U.S. District Court for the District of New Jersey ruled that the U.S. method-of-use patent for Strattera, which expires in 2017, is invalid. We are currently appealing this decision to the U.S. Court of Appeals for the Federal Circuit, with a hearing scheduled in December 2010. The Appeals Court has granted an injunction that prevents the launch generic atomoxetine until a ruling is rendered. While it is difficult to predict the precise impact on Strattera sales, the introduction of generics would result in a rapid and severe decline in our U.S. Strattera sales.

Worldwide sales of Byetta, an injectable product for the treatment of type 2 diabetes, decreased 18 percent and 10 percent to \$168.8 million and \$535.6 million during the third quarter and first nine months of 2010, respectively, due to competitive pressures in the U.S. and German markets. We report as revenue our 50 percent share of Byetta s gross margin in the U.S., 100 percent of Byetta sales outside the U.S., and our sales of Byetta pen delivery devices to Amylin. Our revenues decreased 11 percent and 1 percent to \$102.7 million and \$325.3 million during the third quarter and first nine months of 2010, respectively.

We report as revenue for Erbitux, a product approved to treat various cancers, the net royalties received from our collaboration partners and our product sales. Our revenues decreased 6 percent and 1 percent to \$95.4 million and \$291.6 million during the third quarter and first nine months of 2010, respectively.

Animal health product sales in the U.S. increased 12 percent during the third quarter and first nine months of 2010, respectively, due primarily to increased sales of Comfortis . Sales outside the U.S. increased 13 percent and 15 percent during the third quarter and first nine months of 2010, respectively, driven primarily by increased demand. <u>Gross Margin, Costs, and Expenses</u>

For the third quarter of 2010, gross margins as a percentage of total revenue increased by 1.4 percentage points, to 82.5 percent. For the first nine months of 2010, gross margins as a percentage of total revenue

decreased by 0.9 percentage points, to 81.4 percent. The increase for the third quarter was driven primarily by manufacturing productivity improvements and increased prices. The decrease for the first nine months of 2010 was primarily due to the impact of changes in foreign currencies compared to the U.S. dollar on international inventories sold, which increased cost of sales in the first nine months of 2010, but substantially decreased cost of sales in the first nine months of 2009.

Marketing, selling, and administrative expenses were essentially flat at \$1.69 billion for the third quarter, and increased 3 percent to \$5.06 billion for the first nine months of 2010. For the third quarter, higher marketing and selling expenses outside the U.S. were offset by lower administrative expenses and company-wide cost containment efforts. The increase for the first nine months of 2010 was driven by higher marketing and selling expenses outside the U.S. that were partially offset by lower litigation and administrative expenses and company-wide cost containment. Research and development expenses were \$1.22 billion and \$3.45 billion for the third quarter and first nine months of 2010, respectively. Compared with the same periods of 2009, research and development expenses grew 9 percent and 11 percent for the third quarter and first nine months of 2010, respectively, due primarily to a charge of approximately \$80 million related to the termination of the development of semagacestat and increased costs of late-stage clinical trials.

Acquired IPR&D charges were \$50.0 million in the first nine months of 2010, all of which was associated with the in-license from Acrux in the first quarter. We did not have any acquired IPR&D charges in either the third quarter or first nine months of 2009. We incurred \$59.5 million and \$113.0 of asset impairments, restructuring, and other special charges in the third quarter and first nine months of 2010, respectively, compared with \$549.8 million and \$654.8 million for the same periods in 2009. See Notes 3 and 5 to the consolidated condensed financial statements for additional information.

Other - net, expense (income) improved \$45.2 million and \$196.1 million, to a net expense of \$21.7 million and net income of \$34.4 million for the third quarter and first nine months of 2010, respectively, primarily due to an insurance recovery in the third quarter of 2010 associated with the theft of product at the company s Enfield distribution center in March 2010, as well as lower net interest expense, and, for the first nine months of 2010, damages recovered from generic pharmaceutical companies following Zyprexa patent litigation in Germany and a gain related to the disposition of investment securities acquired in the ImClone acquisition.

The effective tax rate was 22.0 percent and 23.8 percent in the third quarter and first nine months of 2010, respectively, compared with an effective tax rate of 11.9 percent and 19.1 percent in the third quarter and first nine months of 2009, respectively. The effective tax rate for 2010 reflects the expiration of the R&D tax credit in the U.S. The increase in the effective tax rate was driven primarily by the deductibility in the U.S, which has a statutory tax rate higher than our global effective rate, of the asset impairment and restructuring charges in the third quarter of 2009 associated with the sale of the Tippecanoe site and, for the first nine months of 2010, by a one-time deferred tax charge of \$85.1 million associated with the imposition of tax on the prescription drug subsidy of our U.S. retiree health plan as part of U.S. health care reform.

Earnings per share growth of 37 percent and 14 percent in the third quarter and first nine months of 2010, respectively, was higher than revenue growth of 2 percent and 6 percent for the same periods primarily due to lower asset impairments, restructuring, and other special charges.

# FINANCIAL CONDITION

As of September 30, 2010, cash, cash equivalents, and short-term investments totaled \$6.14 billion compared with \$4.50 billion at December 31, 2009. The increase in cash is driven by cash flow from operations of \$4.63 billion, partially offset by dividends paid of \$1.62 billion, acquisitions of

\$797.7 million, purchases of noncurrent investments of \$518.2 million and net purchases of property and equipment of \$443.4 million.

Total debt as of September 30, 2010 increased by \$475.0 million compared with December 31, 2009, to \$7.14 billion, which was due to the approximately \$353 million increase in the fair value of hedged debt and an increase in short-term debt of approximately \$125 million. Our current debt ratings from Standard & Poor s and Moody s are AAand A1, respectively. Our Moody s long-term debt rating is under review for possible downgrade. As of the third quarter of 2010, the U.S. and global economic recoveries proceed but face continued headwinds. Recent U.S. economic data continues to reflect a tepid recovery. Given persistently high unemployment and little sign of near-term inflation risk, the U.S. Federal Reserve is maintaining low interest rates to stimulate lending and economic growth. High sovereign debt levels and efforts at fiscal austerity in the U.S. and other developed countries continue to be a concern for many economists and are predicted to slow economic recovery globally. Given this backdrop, both private and public health care payers are facing heightened fiscal challenges and are taking steps to reduce the costs of care, including pressures for increased pharmaceutical discounts and rebates in the U.S., price cuts in government systems outside the U.S., and efforts to drive greater use of generic drugs globally. We continue to monitor the potential near-term impact of the economic environment on prescription trends, the creditworthiness of our wholesalers and other customers and suppliers, the uncertain impact of recent health care legislation, the federal government s involvement in the economy, and various international government funding levels. We believe that cash generated from operations, along with available cash and cash equivalents, will be sufficient to fund our normal operating needs, including debt service, capital expenditures, acquisition activity, costs associated with litigation and government investigations, and dividends in 2010. We believe that amounts accessible through existing commercial paper markets should be adequate to fund short-term borrowings. Our access to credit markets has not been adversely affected given the high credit quality of our short- and long-term debt. We currently have \$1.24 billion of unused committed bank credit facilities, \$1.20 billion of which backs our commercial paper program and matures in May 2011. Various risks and uncertainties, including those discussed in the Financial Expectations for 2010 section, may affect our operating results and cash generated from operations. We depend on patents or other forms of intellectual property protection for most of our revenues, cash flows, and earnings. In the next three years we will lose effective exclusivity for Zyprexa in October 2011 in the U.S. and in most major European countries in October 2011, and for Humalog in major European countries beginning in November 2010. Gemzar has already lost effective exclusivity in major European countries and we expect to lose effective exclusivity in the U.S. in November 2010. In addition, we face U.S. patent litigation over several key

effective exclusivity in the U.S. in November 2010. In addition, we face U.S. patent litigation over several key patent-protected products whose exclusivity extends beyond 2012, including Alimta, Cymbalta, Evista, and Strattera, and it is possible we could lose our effective exclusivity for one or more of these products prior to the end of 2012. See the Hatch Waxman patent litigation discussion in Note 12 and in the Legal and Regulatory Matters section below. Revenue from each of these products contributes materially to our results of operations, liquidity, and financial position, and the loss of exclusivity would result in a rapid and severe decline in revenue from the affected product, which would have a material adverse effect on our results of operations. However, our goal is to partially mitigate the effect on our operations, liquidity, and financial position through growth in our patent-protected products that do not lose exclusivity during this period, the emerging markets, Japan, and our animal health segment and the previously announced goal to reduce our expected cost structure by \$1 billion by the end of 2011.

#### LEGAL AND REGULATORY MATTERS

We are a party to various legal actions and government investigations. The most significant of these are described below. While it is not possible to determine the outcome of these matters, we believe that, except as specifically noted below, the resolution of all such matters will not have a material adverse effect on our consolidated financial position or liquidity, but could possibly be material to our consolidated results of operations in any one accounting period. Patent Litigation

We are engaged in the following U.S. patent litigation matters brought pursuant to procedures set out in the Hatch-Waxman Act (the Drug Price Competition and Patent Term Restoration Act of 1984):

Cymbalta: Sixteen generic drug manufacturers have submitted Abbreviated New Drug Applications (ANDAs) seeking permission to market generic versions of Cymbalta prior to the expiration of our relevant U.S. patents (the earliest of which expires in 2013). Of these challengers, all allege non-infringement of the patent claims directed to the commercial formulation, and nine allege invalidity (and some also allege nonenforceability) of the patent claims directed to the active ingredient duloxetine. Of the nine challengers to the compound patent claims, one further alleges invalidity of the claims directed to the use of Cymbalta for treating fibromyalgia. In November 2008 we filed lawsuits in U.S. District Court for the Southern District of Indiana against Actavis Elizabeth LLC; Aurobindo Pharma Ltd.; Cobalt Laboratories, Inc.; Impax Laboratories, Inc.; Lupin Limited; Sandoz Inc.; and Wockhardt Limited, seeking rulings that the compound patent claims are valid, infringed, and enforceable. We filed similar lawsuits in the same court against Sun Pharma Global, Inc. in December 2008 and against Anchen Pharmaceuticals, Inc. in August 2009. The cases have been consolidated and actions against all but Wockhardt Limited have been stayed pursuant to stipulations by the defendants to be bound by the outcome of the litigation through appeal. The Wockhardt Limited trial is scheduled to begin in June 2011.

Gemzar: Mayne Pharma (USA) Inc., now Hospira, Inc. (Hospira); Fresenius Kabi Oncology Plc (Fresenius); Sicor Pharmaceuticals, Inc., now Teva Parenteral Medicines, Inc. (Teva); and Sun Pharmaceutical Industries Inc. (Sun) each submitted one or more ANDAs seeking permission to market generic versions of Gemzar prior to the expiration of our relevant U.S. patents (compound patent expiring in 2010 and method-of-use patent expiring in 2013), and alleging that these patents are invalid. Sandoz Inc. (Sandoz), APP Pharmaceuticals, LLC (APP), Actavis Elizabeth LLC and Actavis Totowa LLC (Actavis), Dr. Reddy s Laboratories, Inc. (Dr. Reddy s), and Accord Healthcare Inc. (Accord) have similarly challenged our method-of-use patent. We filed lawsuits in the U.S. District Court for the Southern District of Indiana against Teva (February 2006), Hospira (October 2006, January 2008, and March 2010), APP (December 2009), Fresenius (February 2010), Actavis (June 2010), Sandoz (August 2010), and Dr. Reddy s (October 2010), and against Accord in the U.S. District Court for the Middle District of North Carolina (October 2010), seeking rulings that our patents are valid and are being infringed. In November 2007, Sun filed a declaratory judgment action in the U.S. District Court for the Eastern District of Michigan, seeking rulings that our method-of-use and compound patents are invalid or unenforceable, or would not be infringed by the sale of Sun s generic product. In August 2009, the district court in Michigan granted a motion by Sun for partial summary judgment, invalidating our method-of-use patent, and the opinion was affirmed by a panel of the Court of Appeals for the Federal Circuit. We are seeking reconsideration of this decision. In March 2010, the district court in Indiana upheld the validity of our compound patent. The court also ruled in our favor on all invalidity theories brought forward by Teva on our method-of-use patent, except for obviousness-type double patenting. The court applied collateral estoppel with regard to this theory, given the ruling in the Sun case. We expect the balance of these cases to follow the final outcomes in the Teva and Sun Cases. Teva s ANDAs have been approved by the FDA, and other generic companies have tentative or final marketing approval for generic genetization. Therefore we expect generic gemcitabine to be introduced to the U.S. market as soon as mid-November 2010.

Alimta: Teva Parenteral Medicines, Inc. (Teva); APP; and Barr Laboratories, Inc. (Barr) each submitted ANDAs seeking approval to market generic versions of Alimta prior to the expiration of the relevant U.S. patent (licensed from the Trustees of Princeton University and expiring in 2016), and alleging the patent is invalid. We, along with Princeton, filed lawsuits in the U.S. District Court for the District of Delaware against Teva, APP, and Barr seeking rulings that the compound patent is valid and infringed. Trial is scheduled for November 2010 against Teva and APP.

Evista: In 2006, Teva Pharmaceuticals USA, Inc. (Teva) submitted an ANDA seeking permission to market a generic version of Evista prior to the expiration of our relevant U.S. patents (expiring in 2012-2017) and alleging that these patents are invalid, not enforceable, or not infringed. In June 2006, we filed a lawsuit against Teva in the U.S. District Court for the Southern District of Indiana, seeking a ruling that these patents are valid, enforceable, and being infringed by Teva. In September 2009, the court upheld our method-of-use patents (the last expires in 2014) and the court held that our particle-size patents (expiring 2017) are invalid. Both rulings were upheld by the appeals court in September 2010. InvaGen Pharmaceuticals, Inc. (InvaGen) submitted an ANDA in 2008 seeking approval to market a generic version of Evista prior to the expiration of the particle-size patents at issue in the Teva matter. We filed suit against InvaGen in January 2009 in the U.S. District Court for the Southern District of Indiana That action has been stayed pending the outcome of the Teva appeal. Watson Laboratories Inc. (Watson) also submitted an ANDA in March of 2010 seeking approval to market a generic version of the particle-size patents at issue in the Teva matter. We filed suit against InvaGen District of Indiana That action has been stayed pending the outcome of the Teva appeal. Watson Laboratories Inc. (Watson) also submitted an ANDA in March of 2010 seeking approval to market a generic version of the particle-size patents at issue in the Teva matter. We filed suit against InvaGen District of Indiana.

Strattera: Actavis Elizabeth LLC (Actavis), Apotex Inc. (Apotex), Aurobindo Pharma Ltd. (Aurobindo), Mylan Pharmaceuticals Inc. (Mylan), Sandoz Inc. (Sandoz), Sun Pharmaceutical Industries Limited (Sun), and Teva Pharmaceuticals USA, Inc. (Teva) each submitted an ANDA seeking permission to market generic versions of Strattera prior to the expiration of our relevant U.S. patent (expiring in 2017), and alleging that this patent is invalid. In 2007, we brought a lawsuit against Actavis, Apotex, Aurobindo, Mylan, Sandoz, Sun, and Teva in the United States District Court for the District of New Jersey. In August 2010, the court ruled that our patent is invalid. Several companies have received final approval to market generic atomoxetine, but the Court of Appeals for the Federal Circuit granted an injunction prohibiting the launch of generic atomoxetine until the court renders an opinion. The appeal is scheduled to be heard by the court in December 2010. Zydus Pharmaceuticals (Zydus) filed an action in the New Jersey district court in October 2010 seeking a declaratory judgment that it has the right to launch a generic atomoxetine product, based on the district court ruling. We believe that Zydus is subject to the injunction issued by the court of appeals, and we are considering our legal options.

We believe each of these Hatch-Waxman challenges is without merit and expect to prevail in this litigation. However, it is not possible to determine the outcome of this litigation, and accordingly, we can provide no assurance that we will prevail. An unfavorable outcome in any of these cases could have a material adverse impact on our future consolidated results of operations, liquidity, and financial position.

We have received challenges to Zyprexa patents in a number of countries outside the U.S.:

In Canada, several generic pharmaceutical manufacturers have challenged the validity of our Zyprexa patent (expiring in 2011). In April 2007, the Canadian Federal Court ruled against the first challenger, Apotex Inc. (Apotex), and that ruling was affirmed on appeal in February 2008. In June 2007, the Canadian Federal Court held that an invalidity allegation of a second challenger, Novopharm Ltd. (Novopharm), was justified and denied our request that Novopharm be prohibited from receiving marketing approval for generic olanzapine in Canada. Novopharm began selling generic olanzapine in Canada in the third quarter of 2007. In September 2009, the Canadian Federal Court ruled against us in the Novapharm suit, finding our patent invalid. However, in July 2010 the appeals court set aside the decision and remitted the limited issues of utility and sufficiency of disclosure to the trial court.

In Germany, the German Federal Supreme Court upheld the validity of our Zyprexa patent (expiring in 2011) in December 2008, reversing an earlier decision of the Federal Patent Court. Following the decision of the Supreme Court, the generic companies who launched generic olanzapine based on the earlier decision either agreed to withdraw from the market or were subject to injunction. We have negotiated settlements of the damages arising from infringement with most of the generic companies.

We have received challenges in a number of other countries, including Spain, Austria, Australia, Portugal, and several smaller European countries. In Spain, we have been successful at both the trial and appellate court levels in defeating the generic manufacturers challenges, but additional actions against multiple generic companies are now pending. In March 2010, the District Court of Hague ruled against us and revoked our compound patent in the Netherlands. We have appealed this decision. We have also successfully defended Zyprexa patents in Austria and Portugal.

We are vigorously contesting the various legal challenges to our Zyprexa patents on a country-by-country basis. We cannot determine the outcome of this litigation. The availability of generic olanzapine in additional markets could have a material adverse impact on our consolidated results of operations.

Zyprexa Litigation

We have been named as a defendant in a large number of Zyprexa product liability lawsuits in the U.S. and have been notified of many other claims of individuals who have not filed suit. The lawsuits and unfiled claims (together the

claims ) allege a variety of injuries from the use of Zyprexa, with the majority alleging that the product caused or contributed to diabetes or high blood-glucose levels. The claims seek substantial compensatory and punitive damages and typically accuse us of inadequately testing for and warning about side effects of Zyprexa. Many of the claims also allege that we improperly promoted the drug. Almost all of the federal lawsuits are part of a Multi-District Litigation (MDL) proceeding before The Honorable Jack Weinstein in the Federal District Court for the Eastern District of New York (EDNY) (MDL No. 1596).

Since June 2005, we have entered into agreements with various claimants attorneys involved in U.S. Zyprexa product liability litigation to settle a substantial majority of the claims. The agreements cover a total of approximately 32,690 claimants, including a large number of previously filed lawsuits and other asserted claims. The two primary settlements were as follows:

In 2005, we settled and paid more than 8,000 claims for \$690.0 million, plus \$10.0 million to cover administration of the settlement.

In 2007, we settled and paid more than 18,000 claims for approximately \$500 million.

We are prepared to continue our vigorous defense of Zyprexa in all remaining claims. The U.S. Zyprexa product liability claims not subject to these agreements include approximately 100 lawsuits in the U.S. covering approximately 185 plaintiffs, of which about 75 lawsuits covering about 80 plaintiffs are part of the MDL. The MDL cases have been scheduled for trial in groups, the earliest trial groups have been tentatively scheduled for December 2010. We also have trials scheduled in California in February 2011 and in Texas state court in August 2011.

In January 2009, we reached resolution with the Office of the U.S. Attorney for the Eastern District of Pennsylvania (EDPA), and the State Medicaid Fraud Control Units of 36 states and the District of Columbia, of an investigation related to our U.S. marketing and promotional practices with respect to Zyprexa. As part of the resolution, we pled guilty to one misdemeanor violation of the Food, Drug, and Cosmetic Act

for the off-label promotion of Zyprexa in elderly populations as treatment for dementia, including Alzheimer s dementia, between September 1999 and March 2001. We recorded a charge of \$1.42 billion for this matter in the third quarter of 2008. In 2009, we paid substantially all of this amount, as required by the settlement agreements. As part of the settlement, we have entered into a corporate integrity agreement with the Office of Inspector General (OIG) of the U.S. Department of Health and Human Services (HHS), which requires us to maintain our compliance program and to undertake a set of defined corporate integrity obligations for five years. The agreement also provides for an independent third-party review organization to assess and report on the company systems, processes, policies, procedures, and practices.

In October 2008, we reached a settlement with 32 states and the District of Columbia related to a multistate investigation brought under various state consumer protection laws. While there is no finding that we have violated any provision of the state laws under which the investigations were conducted, we accrued \$62.0 million and agreed to undertake certain commitments regarding Zyprexa for a period of six years, through consent decrees filed with the settling states.

We have been served with lawsuits filed by the states of Alaska, Arkansas, Connecticut, Idaho, Louisiana, Minnesota, Mississippi, Montana, New Mexico, Pennsylvania, South Carolina, Utah, and West Virginia alleging that Zyprexa caused or contributed to diabetes or high blood-glucose levels, and that we improperly promoted the drug. These suits seek to recover the costs paid for Zyprexa through Medicaid and other drug-benefit programs, as well as the costs alleged to have been incurred and that will be incurred by the states to treat Zyprexa-related illnesses. The Alaska case was settled in March 2008 for a payment of \$15.0 million, plus terms designed to ensure, subject to certain limitations and conditions, that Alaska is treated as favorably as certain other states that may settle with us in the future over similar claims. We have reached agreements to settle the Zyprexa-related claims of all of these states except Minnesota, with which we are in advanced discussions. In the second and third quarters of 2009, we incurred pretax charges of \$105.0 million and \$125.0 million, respectively, reflecting the then-current probable and estimable exposures in connection with these claims.

In 2005, two lawsuits were filed in the EDNY purporting to be nationwide class actions on behalf of all consumers and third-party payors, excluding governmental entities, which have made or will make payments for their members or insured patients being prescribed Zyprexa. These actions have now been consolidated into a single lawsuit, which is brought under certain state consumer protection statutes, the federal civil RICO statute, and common law theories, seeking a refund of the cost of Zyprexa, treble damages, punitive damages, and attorneys fees. Two additional lawsuits were filed in the EDNY in 2006 on similar grounds. As with the product liability suits, these lawsuits allege that we inadequately tested for and warned about side effects of Zyprexa and improperly promoted the drug. In September 2008, Judge Weinstein certified a class consisting of third-party payors, excluding governmental entities and individual consumers. We appealed the certification order and Judge Weinstein s order denying our motion for summary judgment in September 2008. In September 2010, both decisions were reversed by the Second Circuit Court of Appeals, which found that the case cannot proceed as a class action and entered a judgment in our favor on plaintiffs overpricing claim. Plaintiffs are seeking a reconsideration of this decision.

We cannot determine with certainty the additional number of lawsuits and claims that may be asserted. The ultimate resolution of Zyprexa product liability and related litigation could have a material adverse impact on our consolidated results of operations, liquidity, and financial position.

Other Product Liability Litigation

We have been named as a defendant in numerous other product liability lawsuits involving primarily diethylstilbestrol (DES), thimerosal, and Byetta. Approximately half of these claims are covered by insurance, subject to deductibles and coverage limits.

### Product Liability Insurance

Because of the nature of pharmaceutical products, it is possible that we could become subject to large numbers of product liability and related claims for other products in the future. In the past several years, we have been unable to obtain product liability insurance due to a very restrictive insurance market. Therefore, for substantially all of our currently marketed products, we have been and expect that we will continue to be completely self-insured for future product liability losses. In addition, there is no assurance that we will be able to fully collect from our insurance carriers in the future.

#### FINANCIAL EXPECTATIONS FOR 2010

We have raised our 2010 earnings per share guidance to a range of \$4.55 to \$4.65, excluding any potential fourth quarter restructuring charges primarily related to previously announced cost structure and global workforce reductions. This new guidance also does not include any potential charges related to the recent news on Bydureon and teplizumab.

We also have revised certain other elements of our full-year 2010 financial guidance. We now expect volume-driven revenue growth in the mid-single digits, driven primarily by Alimta, Cymbalta, Humalog, Cialis, Effient and animal health products. For 2010, we now expect that U.S. health care reform will reduce revenue by approximately \$225 million to \$275 million. We still anticipate that gross margin as a percent of revenue will be flat to increasing. Marketing, selling, and administrative expenses are still projected to grow in the low-single digits while research and development expenses are still projected to grow in the low-double digits. Other-net, expense (income) is now expected to be a net expense of between \$0 and \$50.0 million. Cash flows are still expected to be sufficient to fund capital expenditures (now estimated to be approximately \$700 million), as well as anticipated business development activity and our dividend.

We caution investors that any forward-looking statements or projections made by us, including those above, are based on management s belief at the time they are made. However, they are subject to risks and uncertainties. Actual results could differ materially and will depend on, among other things, the continuing growth of our currently marketed products; developments with competitive products; the implementation of U.S. health care reform; the timing and scope of regulatory approvals and the success of our new product launches; asset impairments, restructurings, and acquisitions of compounds under development resulting in acquired IPR&D charges; foreign exchange rates and global macroeconomic conditions; changes in effective tax rates; wholesaler inventory changes; other regulatory developments, litigation, patent disputes, and government investigations; and the impact of governmental actions regarding pricing, importation, and reimbursement for pharmaceuticals. Other factors that may affect our operations and prospects are discussed in Item 1A of our 2009 Form 10-K, Risk Factors. We undertake no duty to update these forward-looking statements.

# AVAILABLE INFORMATION ON OUR WEBSITE

We make available through our company website, free of charge, our company filings with the Securities and Exchange Commission (SEC) as soon as reasonably practicable after we electronically file them with, or furnish them to, the SEC. The reports we make available include annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, proxy statements, registration statements, and any amendments to those documents. The website link to our SEC filings is http://investor.lilly.com/sec.cfm.

### Item 4. Controls and Procedures

(a) Evaluation of Disclosure Controls and Procedures. Under applicable SEC regulations, management of a reporting company, with the participation of the principal executive officer and principal financial officer, must periodically evaluate the company s disclosure controls and procedures, which are defined generally as controls and other procedures of a reporting company designed to ensure that information required to be disclosed by the reporting company in its periodic reports filed with the commission (such as this Form 10-Q) is recorded, processed, summarized, and reported on a timely basis.

Our management, with the participation of John C. Lechleiter, chairman, president, and chief executive officer, and Derica W. Rice, executive vice president, global services and chief financial officer, evaluated our disclosure controls and procedures as of September 30, 2010, and concluded that they are effective.

(b) Changes in Internal Controls. During the third quarter of 2010, there were no changes in our internal control over financial reporting that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

# PART II. OTHER INFORMATION

#### Item 1. Legal Proceedings

See Part I, Item 2, Management s Discussion and Analysis, Legal and Regulatory Matters, for information on various legal proceedings, including but not limited to:

The U.S. patent litigation involving Alimta, Cymbalta, Evista, Gemzar, and Strattera

The patent litigation outside the U.S. involving Zyprexa

The various federal and state investigations relating to our sales, marketing, and promotional practices

The Zyprexa product liability and related litigation, including claims brought on behalf of state Medicaid agencies and private healthcare payers.

That information is incorporated into this Item by reference.

#### Other Product Liability Litigation

We refer to Part I, Item 3, of our Form 10-K annual report for 2009 for the discussion of product liability litigation involving diethylstilbestrol (DES), vaccines containing the preservative thimerosal, and Byetta. In the DES litigation, we have been named as a defendant in approximately 25 suits involving approximately 50 claimants seeking to recover damages on behalf of children and grandchildren of women who were prescribed DES during pregnancy in the 1950s and 1960s. In December 2009, a lawsuit was filed in the U.S. District Court in Washington, D.C., against us and other manufacturers (*Michele Fecho, et al v. Eli Lilly and Company, et al*) seeking to assert product liability claims on behalf of a putative class of men and women allegedly exposed to the medicine who claim to have later developed breast cancer. In the thimerosal litigation, we have been named as a defendant in approximately 200 suits involving approximately 340 plaintiffs, primarily seeking to recover damages for pancreatitis experienced by patients prescribed Byetta. We are aware of approximately 40 additional claimants who have not yet filed suit.

#### Other Patent Litigation

*Cialis:* In July 2005, Vanderbilt University filed a lawsuit in the United States District Court in Delaware against ICOS Corporation seeking to add three of its scientists as co-inventors on the Cialis compound and method-of-use patents. In January 2009, the district court judge ruled in our favor, declining to add any of these scientists as an inventor on either patent. The plaintiff appealed this ruling to the Court of Appeals for the Federal Circuit, which affirmed the lower court ruling in April 2010, and, in June 2010, further denied a rehearing of the case. The plaintiffs have petitioned for review of this decision by the U.S. Supreme Court. An unfavorable final outcome could have a material adverse impact on our consolidated results of operations, liquidity, and financial position. *Shareholder Derivative Litigation* 

Since January 2008, we have been served with seven shareholder derivative lawsuits: Lambrecht, et al. v. Taurel, et al., filed January 17, 2008, in the U.S. District Court for the Southern District of Indiana; Staehr, et al. v. Eli Lilly and Company, et al., filed March 27, 2008, in Marion County Superior Court in Indianapolis, Indiana; Waldman, et al., v. Eli Lilly and Company, et al., filed February 11, 2008, in the U.S. District Court for the Eastern District of New York; Solomon v. Eli Lilly and Company, et al., filed March 27, 2008, in Marion County Superior Court in Indianapolis, Indiana; Robbins v. Taurel, et al., filed April 9, 2008, in the U.S. District Court for the Eastern District of New York; City of Taylor General Employees Retirement System v. Taurel, et al., filed April 15, 2008, in the U.S. District Court for the Eastern District of New York; and Zemprelli v. Taurel, et al., filed June 24, 2008, in the U.S. District Court for the Southern District of Indiana. All seven lawsuits are nominally filed on behalf of the company, against various current and former directors and officers and allege that the named officers and directors harmed the company through the improper marketing of Zyprexa, and in certain suits, Evista and Prozac. We have reached an agreement with plaintiffs counsel to settle this litigation, which was approved by the U.S. District Court for the Southern District of Indiana and all cases have been dismissed in all courts. Under the settlement, we have agreed to implement or maintain certain enhancements in our corporate governance, compliance, and risk management systems. We also agreed not to oppose plaintiffs counsel s request for fees and expenses of \$8.75 million. **Employment Matters** 

In April 2006, three former employees and one current employee filed a complaint against the company in the U.S. District Court for the Southern District of Indiana (*Welch, et al. v. Eli Lilly and Company*, filed April 20, 2006) alleging racial discrimination. During the litigation, plaintiffs amended their complaint twice, and the lawsuit at one point involved 145 individual plaintiffs as well as the national and local chapters of the National Association for the Advancement of Colored People (NAACP). Although the case was originally filed as a putative class action, in September 2009, plaintiffs withdrew their request for class certification. In September 2010, the court severed the remaining individual claims and ordered that any plaintiff wishing to continue litigation must file an individual action within 90 days; any individual claim not refiled within 90 days will be dismissed with prejudice.

We have also been named as a defendant in a lawsuit filed in the U.S. District Court for the Northern District of New York (*Schaefer-LaRose, et al . v. Eli Lilly and Company*, filed November 14, 2006) claiming that our pharmaceutical sales representatives should have been categorized as non-exempt rather than exempt employees, and claiming that the company owes them back wages for overtime worked, as well as penalties, interest, and attorneys fees. Other pharmaceutical industry participants face similar lawsuits. The case was transferred to the U.S. District Court for the Southern District of Indiana in August 2007. In February 2008, the Indianapolis court conditionally certified a nationwide opt-in collective action under the Fair Labor Standards Act of all current and former employees who served as a Lilly pharmaceutical sales representative at any time from November 2003 to the present. As of the close of the opt-in period, fewer than 400 of the over 7,500 potential plaintiffs elected to participate in the lawsuit. In September 2009, the

District Court granted our motion for summary judgment with regard to Ms. Schaefer-LaRose s claims and ordered the plaintiffs to demonstrate why the entire collective action should not be decertified within 30 days. Plaintiffs have filed a motion for reconsideration of the summary judgment decision and have also opposed decertification. In October 2010, the court denied plaintiffs motion for reconsideration but decided not to decertify the collective action at this time. We believe this lawsuit is without merit and are prepared to defend against it vigorously.

We have been named in a lawsuit brought by the Labor Attorney for 15th Region in the Labor Court of Paulinia, State of Sao Paulo, Brazil, alleging possible harm to employees and former employees caused by exposure to heavy metals. We have also been named in approximately 50 lawsuits filed in the same court by individual former employees making similar claims. We have also been named, along with several other companies, in a lawsuit filed by certain of these individuals in U.S. District Court for the Southern District of Indiana in April 2009, alleging possible harm caused by exposure to pesticides related to our former agricultural chemical manufacturing facility in Cosmopolis, Brazil. In October 2010, the plaintiffs filed a notice of voluntary dismissal in this case.

## Other Matters

Between 2003 and 2005, various municipalities in New York sued us and many other pharmaceutical manufacturers, claiming in general that as a result of alleged improprieties by the manufacturers in the calculation and reporting of average wholesale prices for purposes of Medicaid reimbursement, the municipalities overpaid their portion of the cost of pharmaceuticals. The suits seek monetary and other relief, including civil penalties and treble damages. Similar suits were filed against us and many other manufacturers by the states of Mississippi, Iowa, Utah, Oklahoma, and Kansas. These suits are pending either in the U.S. District Court for the District of Massachusetts or in various state courts. All of these suits are in early stages or discovery is ongoing. We believe these lawsuits are without merit and are prepared to defend against them vigorously.

While it is not possible to predict or determine the outcome of the patent, product liability, or other legal actions brought against us or the ultimate cost of environmental matters, we believe that, except as noted above, the resolution of all such matters will not have a material adverse effect on our consolidated financial position or liquidity but could possibly be material to the consolidated results of operations in any one accounting period.

# Item 1a. Risk Factors

Our business is subject to increasing government price controls and other health care cost containment measures. Government health care cost-containment measures can significantly affect our sales and profitability. In many countries outside the United States, government agencies strictly control, directly or indirectly, the prices at which our products are sold. In the United States, we are subject to substantial pricing pressures from state Medicaid programs and private insurance programs and pharmacy benefit managers, including those operating under the Medicare Part D pharmaceutical benefit, and we expect implementation of recently-enacted U.S. health care reform legislation to increase these pricing pressures. In addition, many state legislative proposals would further negatively affect our pricing and/or reimbursement for our products. We expect pricing pressures from both governments and private payers inside and outside the United States to become more severe. See Management s Discussion and Analysis Executive Overview Legal, Regulatory, and Other Matters.

#### Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

The following table summarizes the activity related to repurchases of our equity securities during the three months ended September 30, 2010:

		Total	Average	Total Number of Shares Purchased as Part of Publicly	Approximate Dollar Value of Shares that May Yet Be
		Number of	Price	Announced	Purchased Under the
		Shares	Paid per	Plans or	Plans
		Purchased	Share	Programs	or Programs
	Period	(a)	(b)	(c)	(d)
		(in		(in	
		thousands)		thousands)	(in millions)
July 2010 August 2010		1	\$ 33.50		\$ 419.2 419.2
September 2010					419.2
Total		1			

The amounts presented in columns (a) and (b) above represent purchases of common stock related to our stock-based compensation programs. The amounts presented in columns (c) and (d) in the above table represent activity related to our \$3.0 billion share repurchase program announced in March 2000. As of September 30, 2010, we have purchased \$2.58 billion related to this program. During the first nine months of 2010, no shares were repurchased pursuant to this program and we do not expect to purchase any shares under this program during the remainder of 2010. *Item 6. Exhibits* 

The following documents are filed as exhibits to this Report:

EXHIBIT 3.	Bylaws as amended October 18, 2010, incorporated by reference from Exhibit 3 to the Company s Report on Form 8-K filed October 21, 2010
EXHIBIT 10.	2007 Change in Control Severance Pay Plan for Select Employees, as amended effective October 18, 2012
EXHIBIT 11.	Statement re: Computation of Earnings per Share
EXHIBIT 12.	Statement re: Computation of Ratio of Earnings to Fixed Charges
EXHIBIT 31.1	Rule 13a-14(a) Certification of John C. Lechleiter, Chairman, President, and Chief Executive Officer

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- EXHIBIT Rule 13a-14(a) Certification of Derica W. Rice, Executive Vice President, Global Services and Chief 31.2 Financial Officer
- EXHIBIT Section 1350 Certification

32.

EXHIBIT Interactive Data File

101.

## SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this Report to be signed on its behalf by the undersigned thereunto duly authorized.

ELI LILLY AND COMPANY (Registrant)

Date: October 29, 2010

/s/ James B. Lootens James B. Lootens Corporate Secretary

Date: October 29, 2010

/s/ Arnold C. Hanish Arnold C. Hanish Vice President, Finance and Chief Accounting Officer

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