

UNIVERSAL CORP /VA/  
Form 10-K  
May 29, 2009  
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**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 March 31, 2009.

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 001-00652

**UNIVERSAL CORPORATION**

(Exact name of registrant as specified in its charter)

**Virginia**  
(State or other jurisdiction of  
incorporation or organization)

**54-0414210**  
(I.R.S. Employer  
Identification Number)

**9201 Forest Hill Avenue**

**Richmond, Virginia**  
(Address of principal executive offices)

**23235**  
(Zip Code)

**Registrant's telephone number, including area code: 804-359-9311**

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

<b>Title of each class</b>	<b>Name of each exchange on</b>
<b>Common Stock, no par value</b>	<b>which registered New York Stock Exchange</b>

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

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

Yes  No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15 (d) of the Act.

Yes  No

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

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Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definitions of large accelerated filer, accelerated filer, and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer  Accelerated filer

Non-accelerated filer  Smaller reporting company

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes  No

The aggregate market value of the registrant's voting and non-voting common equity held by non-affiliates was approximately \$1.1 billion at September 30, 2008.

As of May 22, 2009, the total number of shares of common stock outstanding was 24,999,127.

### **DOCUMENTS INCORPORATED BY REFERENCE**

Certain information contained in the 2009 Proxy Statement for the Annual Meeting of Shareholders of the registrant is incorporated by reference into Part III hereof.

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### **General**

This Form 10-K, which we refer to herein as our Annual Report, contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Among other things, these statements relate to Universal Corporation's financial condition, results of operations and future business plans, operations, opportunities, and prospects. In addition, Universal Corporation and its representatives may from time to time make written or oral forward-looking statements, including statements contained in other filings with the Securities and Exchange Commission and in reports to shareholders. These forward-looking statements are generally identified by the use of words such as we expect, believe, anticipate, could, should, may, plan, will, predict, estimate, and similar words of similar import. These forward-looking statements are based upon management's current knowledge and assumptions about future events and involve risks and uncertainties that could cause actual results, performance, or achievements to be materially different from any anticipated results, prospects, performance, or achievements expressed or implied by such forward-looking statements. Such risks and uncertainties include: anticipated levels of demand for and supply of our products and services; costs incurred in providing these products and services; timing of shipments to customers; changes in market structure; changes in exchange rates; and general economic, political, market, and weather conditions. For a description of factors that may cause actual results to differ materially from such forward-looking statements, see Item 1A, Risk Factors. We caution investors not to place undue reliance on any forward-looking statements as these statements speak only as of the date when made, and we undertake no obligation to update any forward-looking statements made in this report. In addition, the discussion of the impact of current trends on our business in Management's Discussion and Analysis of Financial Condition and Results of Operations Other Information Regarding Trends and Management's Actions in Item 7 should be read carefully in connection with evaluating our business and the forward-looking statements contained in this Annual Report.

This Annual Report uses the terms Universal, the Company, we, us, and our to refer to Universal Corporation and its subsidiaries when it is not necessary to distinguish among Universal Corporation and its various operating subsidiaries or when any distinction is clear from the context in which it is used.

## **PART I**

### **Item 1. Business**

#### **A. The Company**

##### *Overview*

We are the world's leading leaf tobacco merchant and processor. The largest portion of our business involves the procurement, processing, packing, and supply of flue-cured and burley leaf tobacco to manufacturers of consumer tobacco products. The reportable segments for our flue-cured and burley tobacco operations are North America and Other Regions. We also have a third reportable segment, Other Tobacco Operations, which comprises our dark tobacco business, our oriental tobacco joint venture, and certain tobacco-related services. We generated approximately \$2.6 billion in consolidated revenues and earned approximately \$230 million in total segment operating income in fiscal year 2009. Universal Corporation is a holding company that operates through numerous directly and indirectly owned subsidiaries. Universal Corporation's primary subsidiary is Universal Leaf Tobacco Company, Incorporated. See Exhibit 21, Subsidiaries of the Registrant, for additional subsidiary information. Previously, we also owned lumber and building products and agri-products operations; however, we sold those operations in fiscal years 2007 and 2008. We report the assets, liabilities, revenues, and expenses of the lumber and building products and agri-products businesses as discontinued operations for all applicable periods in the accompanying financial statements. Our continuing operations now consist solely of our worldwide tobacco business, which has been our principal focus since our founding in 1918.

##### *Key Operating Principles*

We believe that by following several key operating principles we will continue to produce good financial returns from our business and enhance shareholder value. These key operating principles are:

**Strategic alliances.** We foster strategic alliances with our major customers to the benefit of all parties. These relationships with major manufacturers are, in our opinion, especially appropriate to the leaf tobacco industry where volume at an appropriate price is a

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key factor in long-term profitability. We work to secure adequate factory volumes in all markets where we operate, but we balance that objective with the cost of sourcing incremental volumes in markets where we provide financing to farmers. Alliances permit the optimization of our inventory levels to reduce risk during market downturns by enabling us to target our tobacco purchases against customer purchase indications.

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**Strong local management.** We operate with strong local management in major leaf tobacco markets. We believe that by having strong local management we can better identify and adjust to changes in market conditions. We believe this is a key factor in our ability to continue to deliver the high quality, competitively priced products our customers expect.

**Diversified sources.** We strive to maintain diversified sources of leaf tobacco to minimize reliance on any one growing or sourcing area so long as customers are willing to support such diversity. Although proportions vary with relative crop sizes, historically, South America has provided between 25% and 35% of the aggregate volume of flue-cured and burley tobacco that we handle, and North America and Africa each have provided between 20% and 30% of that aggregate volume.

**Low-cost quality producer.** Our goal is to be the low-cost producer of quality products and services for our customers. We focus on producing a quality product in a cost-effective manner. We sponsor farmer programs in good agricultural practices, the reduction of non-tobacco related materials, and social responsibility, among others.

**Financial strength.** We believe that our financial strength is important, because it enables us to fund our business efficiently, make investments in our business when an appropriate opportunity is identified, and affords us financial flexibility in meeting the needs of our customers. We continually work to improve our creditworthiness.

### *Additional Information*

Our website address is [www.universalcorp.com](http://www.universalcorp.com). We post regulatory filings on this website as soon as reasonably practicable after they are electronically filed with or furnished to the Securities and Exchange Commission. These filings include annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, Section 16 reports on Forms 3, 4, and 5, and any amendments to those reports filed with or furnished to the Securities and Exchange Commission. All such filings on our website are available free of charge. We also post our press releases on our website. Information on our website is not deemed to be incorporated by reference into this Form 10-K.

In addition, our Corporate Governance Guidelines, Code of Conduct, and charters for the Audit Committee, the Executive Committee, the Executive Compensation, Nominating, and Corporate Governance Committee, the Pension Investment Committee, and the Finance Committee are available free of charge to shareholders and the public through the Corporate Governance section of our website. Printed copies of the foregoing are available to any shareholder upon written request to our Treasurer at the address set forth on the cover of this Annual Report.

## **B. Description of Business**

### *General*

Our business involves buying, processing, packing, storing, shipping, and financing leaf tobacco for sale to, or for the account of, manufacturers of consumer tobacco products throughout the world. Buying leaf tobacco involves contracting with and financing farmers in many origins. We do not manufacture cigarettes or other consumer tobacco products. Through various operating subsidiaries and unconsolidated affiliates located in tobacco-growing countries around the world, we process and sell flue-cured and burley tobaccos, dark air-cured tobaccos, and oriental tobaccos. We also provide value-added services to our customers, including blending, chemical and physical testing of tobacco, just-in-time inventory management, and manufacturing reconstituted sheet tobacco. Flue-cured, burley, and oriental tobaccos are used principally in the manufacture of cigarettes, and dark air-cured tobaccos are used mainly in the manufacture of cigars, pipe tobacco, and smokeless tobacco products. We generate our revenues from product sales, processing fees, and fees for other services. Over 80% of our volume is derived from sales to customers with major market positions and with whom we have long-standing relationships. Our sales consist primarily of flue-cured and burley tobaccos. For the fiscal year ended March 31, 2009, our flue-cured and burley operations accounted for 89% of our revenues and 82% of our segment operating income.

Because unprocessed, or green tobacco, is a perishable product, processing of leaf tobacco is an essential service to our customers. Our processing of leaf tobacco includes grading in the factories, blending, quality picking, separation of leaf lamina from the stems, drying, and packing to precise moisture targets for proper aging. Accomplishing these tasks generally requires investment in plants and machinery in areas where the tobacco is grown. Processed tobacco that has been properly packed can be stored by customers for a number of years prior to use, but most processed tobacco is used within two to three years.





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We are a major purchaser and processor in the chief exporting regions for flue-cured and burley tobacco throughout the world. We estimate that we usually purchase between 20% and 30% of the annual production of such tobaccos in Brazil and between 35% and 45% in Africa. These percentages can change from year to year based on the size, price, and quality of the crops. We also have a major processing facility in the United States, which normally handles between 35% and 45% of U.S. flue-cured and burley tobacco production. In the United States, we sell processed U.S. tobacco to cigarette manufacturers, and we process U.S. flue-cured and burley tobacco on a fee basis, which we also refer to as toll processing. We participate in the procurement, processing, and sale of oriental tobacco through ownership of a 49% equity interest in what we believe to be the largest oriental leaf tobacco merchant in the world, Socotab, L.L.C. In addition, we maintain a presence, and in certain cases, a leading presence, in virtually all other major tobacco growing regions in the world. We believe that our leading position in the leaf tobacco industry is based on our operations in all of the major sourcing areas, our development of processing equipment and technologies, our financial position, our ability to meet customer style, volume, and quality requirements, and our long-standing relationships with customers.

We also have a leading position in worldwide dark tobacco markets. Our dark tobacco operations are located in most of the major producing countries and in other smaller markets. Major producing countries for dark tobacco include the United States, the Dominican Republic, Ecuador, Indonesia, Paraguay, the Philippines, Nicaragua, and Brazil. Dark tobaccos are typically used in the manufacture of cigars, pipe tobacco, and smokeless tobacco products, and as components of certain roll-your-own cigarette products.

Sales are made by our sales force and, to a lesser degree, through the use of commissioned agents. Most customers are long-established tobacco product manufacturers.

We conduct our business in varying degrees in a number of countries, including Argentina, Bangladesh, Brazil, Canada, the Dominican Republic, France, Germany, Guatemala, Hungary, India, Indonesia, Italy, Malawi, Mexico, Mozambique, the Netherlands, Nicaragua, Paraguay, the People's Republic of China, the Philippines, Poland, Singapore, South Africa, Spain, Switzerland, Tanzania, Uganda, the United States, Zambia, and Zimbabwe. In addition, Socotab, L.L.C. has oriental tobacco operations in Bulgaria, Greece, Macedonia, and Turkey.

In the majority of the countries where we operate, including Argentina, Brazil, Guatemala, Hungary, Indonesia, Italy, Mexico, Mozambique, the Philippines, Poland, Tanzania, the United States, Zambia, and Zimbabwe, we contract directly with tobacco farmers or tobacco farmer cooperatives, in most cases before harvest, and thereby take the risk that the delivered quality and quantity may not meet market requirements. Outside the United States, we also provide agronomy services and crop advances of, or for, seed, fertilizer, and other supplies. Tobacco in India, and to a certain extent, Malawi, Zambia, and Zimbabwe, is purchased under an auction system.

Our foreign operations are subject to international business risks, including unsettled political conditions, expropriation, import and export restrictions, exchange controls, and currency fluctuations. During the tobacco season in many of the countries listed above, we advance funds, guarantee local loans, or do both, each in substantial amounts, for the purchase of tobacco. The majority of these seasonal advances and loan guarantees mature or terminate in one year or less following the farmers' delivery of contracted tobaccos. Most advances to farmers are denominated in local currency, which is a source of foreign currency exchange rate risk. Most tobacco sales are denominated in U.S. dollars, which reduces our foreign currency exchange risk after the tobacco has been purchased. See Item 1A, Risk Factors for further information about our foreign currency exchange risk.

For a discussion of recent developments and trends in, and factors that may affect, our business, see Item 7, Management's Discussion and Analysis of Financial Condition and Results of Operations, and Item 1A, Risk Factors.

### *Seasonality*

Our operations are seasonal in nature. Tobacco in Brazil is usually purchased from January through July, while buying in Malawi, Mozambique, and other African countries typically begins around April and continues through late fall. Farmers begin to sell U.S. flue-cured tobacco in late July and the marketing season lasts for approximately four months. U.S. burley tobacco farmers deliver their crop from mid-November through mid-February. These overlapping marketing periods tend to mitigate the overall effects of seasonality on our financial performance in most fiscal years.

We normally operate our processing plants for seven to nine months of the year. During this period, inventories of green tobacco, inventories of processed tobacco, and trade accounts receivable normally reach peak levels in succession. We

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normally finance this expansion of current assets with cash and current liabilities, particularly short-term notes payable to banks and customer advances, and these funding sources normally reach their peak usage during this processing period. Our balance sheet at our fiscal year end normally reflects seasonal expansions in working capital in South America, Central America, and Western Europe.

### *Customers*

A material part of our business is dependent upon a few customers. For the year ended March 31, 2009, each of Philip Morris International, Inc., Japan Tobacco Inc., and Imperial Tobacco Group, PLC, including its respective affiliates, accounted for more than 10% of our revenues. The loss of, or substantial reduction in business from, either of these customers or any other significant customer would have a material adverse effect on our results. We have long-standing relationships with these customers.

We had orders from customers for approximately \$462 million of the tobacco in our inventories at March 31, 2009. Based upon historical experience, we expect that at least 90% of such orders will be delivered during the following twelve months. Most of our product requires shipment via oceangoing vessel to reach customer destinations. Delays in the delivery of orders can result from such factors as container availability and port access, or changing customer requirements for shipment.

As more fully described in Note 1 to the consolidated financial statements in Item 8, we recognize sales revenue at the time that title to the tobacco and risk of loss passes to our customer. Individual shipments may be large, and since the customer typically specifies shipping dates, our financial results may vary significantly between reporting periods due to timing of sales. In some markets, principally the United States, we process tobacco that is owned by our customers, and we recognize the revenue for that service when the processing is completed.

### *Competition*

The leaf tobacco industry is highly competitive. Competition among leaf tobacco merchants is based on the ability to meet customer specifications in the buying, processing, and financing of tobacco, and on the price charged for products and services. Competition varies depending on the market or country involved. The number of competitors varies from country to country, but there is competition in most areas to buy the available tobacco. Our principal competitor is Alliance One International, Inc. ( Alliance One ). Alliance One operates in many of the countries where we operate. We believe that we hold the larger worldwide market share based on volume handled by our subsidiaries and affiliates. However, based on our estimates, we do not believe that the market shares differ substantially between the two companies. British American Tobacco PLC, a multinational tobacco product manufacturer, has subsidiaries that also compete with us in some markets. In most major markets, smaller competitors are very active. These competitors typically have lower overhead requirements and provide less support to customers and farmers. Due to their lower cost structures, they can often offer a price on products that is lower than our price. However, we believe that we provide quality controls that are necessary for our customers and make our products highly competitive.

### *Reportable Segments*

We evaluate the performance of our business by geographic region, although the dark air-cured and oriental tobacco businesses are each evaluated on the basis of their worldwide operations. Performance of the oriental tobacco operations is evaluated based on our equity in the pretax earnings of our affiliate. Under this structure, we have the following primary operating segments: North America, South America, Africa, Europe, Asia, Dark Air-Cured, Oriental, and Special Services. North America, South America, Africa, Europe, and Asia are primarily involved in flue-cured and burley leaf tobacco operations for supply to cigarette manufacturers. Dark Air-Cured supplies dark air-cured tobacco principally to manufacturers of cigars, pipe tobacco, and smokeless tobacco products, and Oriental supplies oriental tobacco to cigarette manufacturers. From time to time, the segments may trade in tobaccos that differ from their main varieties, but those activities are not significant to their overall results. Special Services provides just-in-time inventory services for certain customers and laboratory services including physical and chemical product testing for customers.

The five regional operating segments serving our cigarette manufacturer customers share similar characteristics in the nature of their products and services, production processes, class of customer, product distribution methods, and regulatory environment. Based on the applicable accounting guidance, four of the regions South America, Africa, Europe, and Asia are aggregated into a single reporting segment, Other Regions, because they also have similar economic characteristics. North America is reported as an individual operating segment because its economic characteristics differ from the other regions, generally because its operations do not require significant working capital investments for crop financing and inventory and because toll processing is an important source of its operating income. The Dark Air-Cured, Oriental, and Special Services segments, which have differing characteristics in some of the categories mentioned above, are reported together as Other Tobacco Operations because each is below the measurement threshold for separate reporting.



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### *Financial Information about Segments*

Our North America and Other Regions reportable segments, which represent our flue-cured and burley tobacco operations, accounted for 16% and 73% of our revenues and 21% and 61% of our segment operating income, respectively, in fiscal year 2009. Our Other Tobacco Operations reportable segment accounted for 11% of our revenues and 18% of our segment operating income in fiscal year 2009. Sales and other operating revenues and operating income attributable to our reportable segments for each of the last three fiscal years, along with segment assets for each reportable segment at March 31, 2009, 2008, and 2007, are set forth in Note 16 to the consolidated financial statements which are included in Item 8 of this Annual Report. Information with respect to the geographic distribution of our revenues and long-lived assets is also set forth in Note 16 to the consolidated financial statements.

### **C. Employees**

We employed over 24,000 employees throughout the world during the fiscal year ended March 31, 2009. This figure is estimated because the majority of our personnel are seasonal employees.

### **D. Research and Development**

No material amounts were expended for research and development during the fiscal years ended March 31, 2009, 2008, or 2007.

### **E. Patents, etc.**

We hold no material patents, licenses, franchises, or concessions.

### **F. Government Regulation, Environmental Matters and Other Matters**

Our business is subject to general governmental regulation in the United States and in foreign jurisdictions where we conduct business. Such regulation includes, but is not limited to, matters relating to environmental protection. To date, governmental provisions regulating the discharge of material into the environment have not had a material effect upon our capital expenditures, earnings, or competitive position. See Item 1A, Risk Factors for a discussion of government regulations and other factors that may affect our business.

### **Item 1A. Risk Factors**

#### **Operating Factors**

*The leaf tobacco industry is highly competitive, and we are heavily reliant on a few large customers.*

We are one of two major independent global competitors in the highly competitive leaf tobacco industry, both of whom are reliant upon a few large customers. The loss of one of those large customers or a significant decrease in their demand for our products or services could significantly decrease our sales of products or services, which would have a material adverse effect on our results of operations. The competition among leaf tobacco merchants is based on the ability to meet customer specifications in the buying, processing, and financing of tobacco, and on the price charged for products and services. We believe that we consistently meet our customers' specifications and charge competitive prices. Because we rely upon a few significant customers, the consolidation or failure of any of these large or significant customers could contribute to a significant decrease in our sales of products and services.

We have seen an increase in competition from small competitors in some of the markets where we conduct business. Some of these competitors have grown to operate in more than one country. These small competitors typically have lower overhead requirements. They provide little or no support to farmers. Due to their lower cost structures, they often can offer a price on products that is lower than our price. If our customers shift significant purchases to these smaller competitors, our financial results could be negatively impacted.



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*Our financial results can be significantly affected by changes in the balance of supply and demand for leaf tobacco.*

Because we are a leaf tobacco merchant, our financial results can be significantly affected by changes in the overall balance of worldwide supply and demand for leaf tobacco. The demand for tobacco, which is based upon customers' expectations of their future requirements, can change from time to time depending upon internal and external factors affecting the demand for their products. Our customers' expectations, and thus their demand for leaf tobacco, are influenced by a number of factors, including:

trends in the global consumption of cigarettes,

trends in sales of cigars and other tobacco products, and

levels of competition among our customers.

The world supply of leaf tobacco at any given time is a function of current tobacco production, inventories held by manufacturers, and the volumes of uncommitted stocks of processed tobacco held by leaf tobacco merchants from prior years' production. Production of tobacco in a given year may be significantly affected by such factors as:

weather and natural disasters,

crop infestation and disease,

volume of annual tobacco plantings and yields realized by farmers,

farmers electing to grow crops other than tobacco,

elimination of government subsidies to farmers, and

demographic shifts reducing the number of farmers or the amount of land available to grow tobacco.

Any significant change in these factors could cause a material imbalance in the supply and demand for tobacco, which would affect our results of operations.

*Our financial results will vary according to growing conditions, customer requirements, and other factors. These factors also limit the ability to accurately forecast our future performance and increase the risk of an investment in our common stock or other securities.*

Our financial results, particularly our year-over-year quarterly comparisons, may be significantly affected by variations in tobacco growing seasons and fluctuations in crop sizes. The timing of the cultivation and delivery of tobacco is dependent upon a number of factors, including weather and other natural events, and our processing schedules and results of operations can be significantly altered by these factors.

Further, the timing and unpredictability of customer orders and shipments may require us to keep tobacco in inventory, increase our risk, and result in variations in quarterly and annual financial results. We base sales recognition on the passage of ownership, usually with shipment of product. Since individual shipments may represent significant amounts of revenue, our quarterly and annual financial results may vary significantly depending on the needs and shipping instructions of our customers and the availability of transportation services. These fluctuations result in varying volumes and sales in given periods, which also reduce the comparability of financial results for different periods or for the same

periods in different years.

*Major shifts in customer requirements for tobacco supply may significantly affect our operating results.*

If our customers significantly alter their requirements for tobacco volumes from certain regions, we may have to change our production facilities and alter our fixed asset base in certain origins. Permanent or long-term reduction in demand for tobacco from origins where we have operations may trigger restructuring and impairment charges. We may also need to make significant capital investments in other regions to develop the needed infrastructure to meet customer supply requirements.

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*In areas where we purchase leaf tobacco directly from farmers, we bear the risk that the tobacco we receive will not meet quality and quantity requirements.*

When we contract directly with tobacco farmers or tobacco farmer cooperatives, which is the method we use to purchase tobacco in most countries, we bear the risk that the tobacco delivered may not meet customer quality and quantity requirements. If the tobacco does not meet such market requirements, we may not be able to meet all of our customers' orders, and such failure would have an adverse effect on profitability and results of operations. Because in a contract market we buy all of the farmers' production, which encompasses many styles, we also have a risk that not all of that production will be readily marketable. In addition, in many foreign countries where we purchase tobacco directly from farmers, we provide them with financing. Unless we receive marketable tobacco that meets the quality and quantity specifications of our customers, we bear the risk that we will not be able to fully recover our crop advances or recover them in a reasonable period of time.

*Weather and other conditions can affect the marketability of our products.*

Tobacco crops are subject to vagaries of weather and the environment that can, in some cases, change the quality or size of the crops. If a weather event is particularly severe, such as a major drought or hurricane, the affected crop could be destroyed or damaged to an extent that it would be less desirable to manufacturers, which would result in a reduction in revenues. If such an event is also widespread, it could affect our ability to acquire the quantity of products required by our customers. In addition, other factors can affect the marketability of tobacco, including, among other things, the presence of:

excess residues of pesticides, fungicides, and herbicides,

foreign matter, and

genetically modified organisms.

A significant event impacting the condition or quality of a large amount of any of the crops that we buy could make it difficult for us to sell these products or to fill customers' orders.

### **Regulatory and Governmental Factors**

*Government efforts to regulate the production and consumption of tobacco products could have a significant impact on the businesses of our customers, which would, in turn, affect our results of operations.*

The U.S. federal government and certain state and local governments have taken or proposed actions that may have the effect of reducing U.S. consumption of tobacco products and indirectly reducing demand for our products and services. These activities have included:

restrictions on the use of tobacco products in public places and places of employment,

proposed legislation authorizing the U.S. Food and Drug Administration to regulate the manufacturing and marketing of tobacco products,

increases in the federal, state, and local excise taxes on cigarettes and other tobacco products, and

the policy of the U.S. government to link certain federal grants to the enforcement of state laws restricting the sale of tobacco products. Numerous other legislative and regulatory anti-smoking measures have been proposed at the federal, state, and local levels. The United States represents only 11% of the world market for cigarette production outside of the People's Republic of China.



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A number of foreign governments and global non-government organizations also have taken or proposed steps to restrict or prohibit tobacco product advertising and promotion, to increase taxes on tobacco products, and to discourage tobacco product consumption. A number of such measures are included in the Framework Convention on Tobacco Control ( FCTC ), which was negotiated and promoted globally under the auspices of the World Health Organization ( WHO ). We cannot predict the extent to which the efforts of governments or non-governmental agencies to reduce tobacco consumption might affect the business of our primary customers. However, a significant decrease in worldwide tobacco consumption brought about by existing or future governmental laws and regulations would reduce demand for our products and services and could have a material adverse effect on our results of operations.

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*Government actions can have a significant effect on the sourcing of tobacco. If some of the current efforts are successful, we could have difficulty obtaining sufficient tobacco to meet our customers' requirements, which could have an adverse effect on our performance and results of operations.*

The WHO, through the FCTC, has created a formal study group to identify and assess crop diversification initiatives and alternatives to leaf tobacco growing in countries whose economies depend upon tobacco production. The study group began its work in February 2007. If certain countries were to partner with the FCTC study group and seek to eliminate or significantly reduce leaf tobacco production, we could encounter difficulty in sourcing leaf tobacco to fill customer requirements, which could have an adverse effect on our results of operations.

*Because we conduct a significant portion of our operations internationally, political and economic uncertainties in certain countries could have an adverse effect on our performance and results of operations.*

Our international operations are subject to uncertainties and risks relating to the political stability of certain foreign governments, principally in developing countries and emerging markets, and also to the effects of changes in the trade policies and economic regulations of foreign governments. These uncertainties and risks, which include undeveloped or antiquated commercial law, the expropriation or nationalization of assets, and the authority to revoke or refuse to renew business licenses and work permits, may adversely impact our ability to effectively manage our operations in those countries. For example, in the past, we have experienced significant year-to-year fluctuations in earnings due to changes in the Brazilian government's economic policies, and government actions in Zimbabwe have reduced the tobacco crop there, causing us to shift sourcing of tobacco to other countries. We have substantial capital investments in South America and Africa, and the performance of our operations in those regions can materially affect our earnings. If the political situation in any of the countries where we conduct business were to deteriorate significantly, our ability to recover assets located there could be impaired. To the extent that we do not replace any lost volumes of tobacco with tobacco from other sources, or we incur increased costs related to such replacement, our results of operations would suffer.

*Changes in tax laws in the countries where we do business may adversely affect our results of operations.*

Through our subsidiaries, we are subject to the tax laws of many jurisdictions. Changes in tax laws or the interpretation of tax laws can affect our earnings, as can the resolution of various pending and contested tax issues. In most jurisdictions, we regularly have audits and examinations by the designated tax authorities, and additional tax assessments are common. We believe that we routinely comply with applicable tax laws in the jurisdictions where we operate, and we vigorously contest all significant tax assessments where we believe we are in compliance with the tax laws.

## **Financial Factors**

*Failure of our customers or farmers to repay extensions of credit could materially impact our results of operations.*

We extend credit to both farmers and customers. A significant bad debt provision related to amounts due could adversely affect our results of operations. In addition, crop advances to farmers are generally secured by the farmers' agreement to deliver green tobacco. In the event of crop failure, delivery failure, or permanent reductions in crop sizes, full recovery of advances may never be realized, or otherwise could be delayed until future crops are delivered. See Notes 1 and 15 to the consolidated financial statements in Item 8 for more information on these extensions of credit.

*Fluctuations in foreign currency exchange rates may affect our results of operations.*

We account for most of our tobacco operations using the U.S. dollar as the functional currency. The international tobacco trade generally is conducted in U.S. dollars, and we finance most of our tobacco operations in U.S. dollars. This generally limits foreign exchange risk to the economic risk that is related to leaf purchase and production costs, overhead, and income taxes in the source country. Significant currency movements could materially impact our results of operations. Changes in exchange rates can make a particular crop more or less expensive in U.S. dollar terms. If a particular crop is viewed as expensive in U.S. dollar terms, it may be less attractive in the world market. This could negatively affect the profitability of that crop and our results of operations. In certain tobacco markets that are primarily domestic, we use the local currency as the functional currency. Examples of these markets are Hungary, Poland, and the Philippines. In other markets, such as Western Europe, where export sales have been denominated primarily in local currencies, we also use the local currency as the functional currency. In these markets, reported earnings are affected by the translation of the local currency into the U.S. dollar. See Item 7A, "Qualitative and Quantitative Disclosure About Market Risk" for additional discussion related to foreign currency exchange risk.



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Our purchases of tobacco are generally made in local currency, and we also provide farmer advances that are denominated in the local currency. We account for currency remeasurement gains or losses on those advances as period costs, and they are usually accompanied by offsetting increases or decreases in the purchase cost of tobacco, which is priced in the local currency. The effect of differences in the cost of tobacco is generally not realized in our earnings until the tobacco is sold, which often occurs in a quarter or fiscal year subsequent to the recognition of the related remeasurement gains or losses. The difference in timing could affect our profitability in a given quarter or fiscal year. During fiscal year 2009, we recorded remeasurement losses of more than \$40 million related to a significant devaluation of the Brazilian currency. However, our purchases of the 2009 Brazilian crop, which will be marketed primarily in our fiscal year 2010, are expected to be at a lower cost in U.S. dollar terms due to the devaluation.

We have used currency hedging strategies to reduce our foreign currency exchange rate risks in some markets. In addition, where there are no active forward foreign exchange markets in countries where we source tobacco, we often manage our foreign exchange risk by matching funding for inventory purchases with the currency of sale and by minimizing our net investment in these countries. To the extent that we have net monetary assets or liabilities in local currency, we may have currency remeasurement gains or losses that will affect our results of operations.

*Changes in interest rates may affect our results of operations.*

In our business, customers usually either pre-finance purchases or pay market rates of interest for inventory purchased on order. From time to time, we borrow long-term debt at fixed rates. Through hedging agreements, we may swap the interest rates on our existing fixed-rate debt to floating market interest rates to better match the interest rates that we charge our customers. To the extent we are unable to match these interest rates, a decrease in short-term interest rates could increase our net financing costs. In addition, at times we may have significant amounts of cash invested. Decreases in short-term interest rates reduce the income we derive from those investments.

*Low investment performance by our defined benefit pension plan assets may increase our pension expense, and may require us to fund a larger portion of our pension obligations, thus, diverting funds from other potential uses.*

We sponsor a domestic defined benefit pension plan that covers certain eligible employees. Our pension expense and required contributions to our pension plan are directly affected by the value of plan assets, the projected rate of return on plan assets, the actual rate of return on plan assets, and the actuarial assumptions we use to measure the defined benefit pension plan obligations.

Due to the significant market downturn that began in 2008, plan asset values declined significantly. If plan assets continue to perform below the assumed rate of return used to determine pension expense, future pension expense will increase. Further, as a result of the global economic instability, our pension plan investment portfolio has recently incurred greater volatility.

We establish the discount rate used to determine the present value of the projected and accumulated benefit obligations at the end of each fiscal year based upon the available market rates for high quality, fixed income investments. We match the projected cash flows of our pension and other postretirement benefit plans against those generated by high-quality corporate bonds. The yield of the resulting bond portfolio provides a basis for the selected discount rate. An increase in the discount rate would reduce the future pension and other postretirement benefit expense and, conversely, a decrease in the discount rate would increase that expense.

In addition, the proportion of pension assets to liabilities, which is called the funded status, determines the level of contribution to the plan that is required by law. In recent years, we have funded the plan in amounts in excess of that requirement, but changes in the plan's funded status related to the value of assets or liabilities could increase the amount required to be funded. In fiscal year 2009, we contributed \$15.7 million to our domestic plan, and based on current guidelines, assumptions and estimates, we anticipate that we will make a cash contribution of approximately \$2.7 million to our domestic ERISA pension plan in fiscal year 2010. Changes in the current assumptions and estimates could result in a greater contribution in fiscal years beyond 2010. We cannot predict whether changing market or economic conditions, regulatory changes or other factors will further increase our pension and other postretirement expense or funding obligations, diverting funds we would otherwise apply to other uses.

### **Item 1B. Unresolved Staff Comments**

None

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Except as noted, we own the following significant properties (greater than 500,000 square feet):

Location	Principal Use	Area (Square Feet)
<b>Flue-Cured and Burley Leaf Tobacco Operations:</b>		
<b>North America:</b>		
<b>United States</b>		
Nash County, North Carolina	Factory and storages	1,284,000
<b>Canada</b>		
Simcoe, Ontario	Factory and storages	569,000
<b>Other Regions:</b>		
<b>Brazil</b>		
Santa Cruz	Factory and storages	2,492,000
Joinville <sup>(1)</sup>	Factory and storages	1,097,000
Venancio Aires	Storages	860,000
<b>Malawi</b>		
Lilongwe	Factory and storages	1,194,000
<b>Mozambique</b>		
Tete	Factory and storages	737,000
<b>Tanzania</b>		
Morogoro	Factory and storages	798,000
<b>Zimbabwe</b>		
Harare <sup>(2)</sup>	Factory and storages	1,342,000
<b>Other Tobacco Operations:</b>		
<b>United States</b>		
Lancaster, Pennsylvania	Factory and storages	636,000

<sup>(1)</sup> Leased from a third party.

<sup>(2)</sup> Owned by an unconsolidated subsidiary.

We lease office space of about 45,000 square feet at 9201 Forest Hill Avenue in Richmond, Virginia, where we are headquartered, and which is adequate for our needs. We also own the land and building located at 1501 North Hamilton Street in Richmond, Virginia, which contains approximately 83,000 square feet of floor space. That property was used as our headquarters until March 2009 and is currently for sale.

Our business involves, among other things, storing and processing green tobacco and storing processed tobacco. We operate processing facilities in major tobacco growing areas. In addition, we require tobacco storage facilities that are in close proximity to the processing facilities. We own most of the tobacco storage facilities, but we lease additional space as needs arise, and expenses related to such leases are not material. We believe that the properties currently utilized in our tobacco operations are maintained in good operating condition and are suitable and adequate for our purposes at our current volumes.

In addition to our significant properties listed above, we own other processing facilities in the following countries: Germany, Hungary, Italy, the Netherlands, the Philippines, Poland, and the United States. In addition, we have ownership interests in processing plants in Guatemala and Mexico and have access to processing facilities in other areas, such as Argentina, India, the People's Republic of China, South Africa, Uganda, and Zambia. Socotab L.L.C., an oriental tobacco joint venture in which we own a minority interest, owns tobacco processing plants in Turkey, Macedonia, Greece, and Bulgaria.

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Except for the Lancaster, Pennsylvania facility, the facilities described above are engaged primarily in processing tobacco used by manufacturers in the production of cigarettes. The Lancaster facility and another facility in Virginia, as well as facilities in Brazil, the Dominican Republic, Indonesia, and Paraguay, process tobacco used in making cigar, pipe, and smokeless products, as well as components of certain roll-your-own products. At the end of fiscal year 2010, processing for this type of tobacco at the Virginia facility will be consolidated into the Lancaster facility.

### **Item 3. Legal Proceedings**

#### *European Commission Fines in Spain*

In October 2004, the European Commission (the Commission) imposed fines on five companies active in the raw Spanish tobacco processing market totaling 20 million for colluding on the prices paid to, and the quantities bought from, the tobacco growers in Spain. Two of our subsidiaries, Tabacos Espanoles S.A. (TAES), a purchaser and processor of raw tobacco in Spain, and Deltafina, S.p.A. (Deltafina), an Italian subsidiary, were among the five companies assessed fines. In its decision, the Commission imposed a fine of 108,000 on TAES, and a fine of 11.88 million on Deltafina. Deltafina did not and does not purchase or process raw tobacco in the Spanish market, but was and is a significant buyer of tobacco from some of the Spanish processors. We recorded a charge of about 12 million (approximately \$14.9 million at the September 2004 exchange rate) in the second quarter of fiscal year 2005 to accrue the full amount of the fines assessed against our subsidiaries.

In January 2005, Deltafina filed an appeal in the Court of First Instance of the European Communities. The main ground of appeal is that the Commission erred in imposing liability on Deltafina as a cartel participant, particularly as the cartel leader, when Deltafina was not an actual party to the agreement and was incapable of acting in the relevant market. In addition, Deltafina argues that (i) the Commission failed to allege that Deltafina was a member of the cartel and cartel leader prior to issuing its decision, thereby impairing Deltafina's right to defend itself, and (ii) that the Commission failed to try to prove that the practices affected trade between Member States of the European Community. The appeal also argues that the Commission incorrectly calculated the amount of the Deltafina fine. The outcome of the appeal is uncertain, and an ultimate resolution to the matter could take several years. Deltafina has deposited funds in an escrow account with the Commission in the amount of the fine in order to stay execution during the appeal process. This deposit is classified as a non-current asset.

#### *European Commission Fines in Italy*

In 2002, we reported that we were aware that the Commission was investigating certain aspects of the tobacco leaf markets in Italy. Deltafina buys and processes tobacco in Italy. We reported that we did not believe that the Commission investigation in Italy would result in penalties being assessed against us or our subsidiaries that would be material to our earnings. The reason we held this belief was that we had received conditional immunity from the Commission because Deltafina had voluntarily informed the Commission of the activities that were the basis of the investigation.

On December 28, 2004, we received a preliminary indication that the Commission intended to revoke Deltafina's immunity for disclosing in April 2002 that it had applied for immunity. Neither the Commission's Leniency Notice of February 19, 2002, nor Deltafina's letter of provisional immunity contains a specific requirement of confidentiality. The potential for such disclosure was discussed with the Commission in March 2002, and the Commission never told Deltafina that the disclosure would affect Deltafina's immunity. On November 15, 2005, we received notification that the Commission had imposed fines totaling 30 million (about \$40 million at the March 31, 2009 exchange rate) on Deltafina and Universal Corporation jointly for infringing European Union antitrust law in connection with the purchase and processing of tobacco in the Italian raw tobacco market.

We do not believe that the decision can be reconciled with the Commission's Statement of Objections and facts. Both Deltafina and Universal Corporation have appealed the decision to the Court of First Instance of the European Communities. Based on consultation with outside legal counsel, we believe it is probable that we will prevail in the appeals process, and we have not accrued a charge for the fine. Deltafina has provided a bank guarantee to the Commission in the amount of the fine in order to stay execution during the appeals process.

#### *U.S. Foreign Corrupt Practices Act*

As a result of a posting to our Ethics Complaint hotline alleging improper activities that involved or related to certain of our tobacco subsidiaries, the Audit Committee of our Board of Directors engaged an outside law firm to conduct an investigation of the alleged activities. That investigation revealed that there have been payments that may have violated the U.S. Foreign Corrupt Practices Act. At this time, the payments involved appear to have approximated \$2 million over a seven-year period. In addition, the investigation revealed activities in foreign jurisdictions that may have violated the



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competition laws of such jurisdictions, but we believe those activities did not violate U.S. antitrust laws. We voluntarily reported these activities to the appropriate U.S. authorities in March 2006. On June 6, 2006, the Securities and Exchange Commission notified us that a formal order of investigation had been issued.

If the U.S. authorities determine that there have been violations of the Foreign Corrupt Practices Act, or if the U.S. authorities or the authorities in foreign jurisdictions determine there have been violations of other laws, they may seek to impose sanctions on us or our subsidiaries that may include injunctive relief, disgorgement, fines, penalties, and modifications to business practices. It is not possible to predict at this time what sanctions they might seek to impose. It is also not possible to predict how the government's investigation or any resulting sanctions may impact our business, financial condition, results of operations, or financial performance, although such sanctions, if imposed, could be material to our results of operations in any quarter. We will continue to cooperate with the authorities in these matters.

*Other Legal Matters*

In addition to the above-mentioned matters, some of our subsidiaries are involved in other litigation or legal matters incidental to their business activities. While the outcome of these matters cannot be predicted with certainty, we are vigorously defending the claims and do not currently expect that any of them will have a material adverse effect on our financial position. However, should one or more of these matters be resolved in a manner adverse to our current expectation, the effect on our results of operations for a particular fiscal reporting period could be material.

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

No matters were submitted to a vote of security holders during the quarter ended March 31, 2009.



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

Our common stock is traded on the New York Stock Exchange ( NYSE ) under the symbol UVV. The following table sets forth the high and low sales prices per share of the common stock on the NYSE Composite Tape, based upon published financial sources, and the dividends declared on each share of common stock for the quarter indicated.

		First Quarter	Second Quarter	Third Quarter	Fourth Quarter
<b>2009</b>					
Cash dividends declared	\$	0.45	\$ 0.45	\$ 0.46	\$ 0.46
Market price range	High	<p>In January 2007, our Board of Directors approved a plan to restructure and eventually sell or close our collagen manufacturing facility in Fremont, California that we acquired in the Inamed acquisition. This plan is the result of a reduction in anticipated future market demand for human and bovine collagen products. In connection with the restructuring and eventual sale or closure of the facility, we estimate that total pre-tax charges for severance, lease termination and contract settlement costs will be between \$6.0 million and \$8.0 million, all of which are expected to be cash expenditures. The foregoing estimates are based on assumptions relating to, among other things, a reduction of approximately 69 positions, consisting principally of manufacturing positions at our facility. We expect to begin to record these costs in the first quarter of 2007 and expect to continue to incur them up through and including the fourth quarter of 2008. Prior to any closure of our facility, we intend to manufacture a sufficient quantity of inventories of our collagen products to meet estimated market demand through 2010.</p> <p><i>Hylaform® Gel.</i> <i>Hylaform®</i> gel dermal fillers are an avian-based, cross-linked hyaluronic acid injectable product for the treatment of facial wrinkles and scars, which are approved for sale and marketing in Canada, Europe and the United States. We license <i>Hylaform®</i> from Genzyme Corporation. <i>Hylaform®</i> does not require a skin test, so patients can be treated immediately. In 2001, two new formulations of <i>Hylaform®</i> gel</p>			

were developed: *Hylaform*<sup>®</sup> FineLine, designed especially for people with fine line wrinkles or superficial facial contour defects, and *Hylaform*<sup>®</sup> Plus, formulated for treating deeper depressions and more pronounced contour problems such as deeper scars, lines, and furrows. We launched *Hylaform*<sup>®</sup> FineLine and *Hylaform*<sup>®</sup> Plus in Europe in September 2001. In December 2001, Health Canada's Therapeutic Products Programme, or HCTPP, granted Genzyme Corporation a Medical Device License for *Hylaform*<sup>®</sup> gel. In January 2002, the HCTPP approved both *Hylaform*<sup>®</sup> Plus and *Hylaform*<sup>®</sup> FineLine. In April 2004, Inamed received approval from the FDA to market and sell *Hylaform* gel in the United States. In October 2004, the FDA granted market approval for *Hylaform*<sup>®</sup> Plus in the United States.

*Juvéderm*<sup>™</sup>/*Hydrafil*<sup>™</sup>. Our product *Juvéderm*<sup>™</sup> is a non-animal based, cross-linked hyaluronic acid-based dermal filler, and is indicated for wrinkle correction, facial contouring and lip enhancements. This technology is based on the delivery of a homogeneous gel-based hyaluronic acid, as opposed to a particle gel-based hyaluronic acid technology, which is used in other products. Inamed had obtained the rights to develop, distribute and market *Juvéderm*<sup>™</sup> dermal fillers (including product lines and extensions) from Groupe Cornéal Laboratoires, or Cornéal, in January 2004. Inamed's rights were exclusive in the United States, Canada, and Australia, and non-exclusive in France, Spain, the United Kingdom, Italy, Germany and Switzerland. In these European countries, *Juvéderm*<sup>™</sup> is marketed under the trademark *Hydrafil*<sup>™</sup>. *Juvéderm*<sup>™</sup> and *Hydrafil*<sup>™</sup> are each currently available in five formulations for soft tissue augmentation of varying severities of wrinkles. Through our January 2007 acquisition of Cornéal, we expanded our marketing rights to *Juvéderm*<sup>™</sup>, *Surgiderm*<sup>®</sup>, *Voluma*<sup>®</sup> and other hyaluronic acid dermal fillers to all countries worldwide and obtained control over the manufacturing process and future development of *Juvéderm*<sup>™</sup> and the company's R&D pipeline. *Juvéderm*<sup>™</sup> products are currently approved or registered in over 34 countries, including all major European markets. In these markets, *Juvéderm*<sup>™</sup> does not require a skin test pre-treatment. Distribution of *Juvéderm*<sup>™</sup> in Canada and key European markets commenced in

2004. In June 2006, the FDA approved the *Juvéderm*<sup>™</sup> dermal filler family of products and in September 2006, we launched the next-generation hyaluronic acid-based dermal filler products, *Juvéderm*<sup>™</sup> Ultra and *Juvéderm*<sup>™</sup> Ultra Plus through an experience trial with a group of physicians with expertise in facial aesthetics, in advance of U.S. product availability, which commenced in January 2007.

*Captique*<sup>™</sup>. *Captique*<sup>™</sup> dermal filler is a non-animal stabilized hyaluronic acid injectable product indicated for the correction of moderate to severe facial wrinkles and scars. We license *Captique*<sup>™</sup> from Genzyme Corporation. *Captique*<sup>™</sup> does not require a skin test, so patients can be treated immediately. We commenced sales of the product in the United States in January 2005.

#### ***Obesity Intervention***

We develop, manufacture, and market several devices for the treatment of obesity. Our principal product in this market area, the *LAP-BAND*<sup>®</sup> System, is designed to provide minimally invasive long-term treatment of severe obesity and is used as an alternative to more invasive procedures such as gastric bypass surgery or stomach stapling. The *LAP-BAND*<sup>®</sup> System is an adjustable silicone elastomer band which is laparoscopically placed around the upper part of the stomach through a small incision, creating a small pouch at the top of the stomach. This new pouch fills faster to make the patient feel full sooner, and regulates the passage of food to retain that feeling of fullness for

longer periods of time. Unlike other obesity surgeries that are permanent, the *LAP-BAND*<sup>®</sup> System procedure is adjustable and reversible.

The *LAP-BAND*<sup>®</sup> System has achieved widespread acceptance in the United States, Europe, Australia, Latin America, the Middle East, and other countries around the world. In 2001, the FDA approved the *LAP-BAND*<sup>®</sup> System for the treatment of severe obesity in adults who have failed more conservative weight reduction alternatives. In April 2004, Inamed introduced the *LAP-BAND VG*<sup>®</sup>, which was approved by the FDA in January 2004. The *LAP-BAND VG*<sup>®</sup> meets the needs of a wider range of patients, allowing us to serve a broader market. The larger band circumference of the *LAP-BAND VG*<sup>®</sup> serves those who are physically larger, have thicker gastric walls, or have substantial internal fat. Over 300,000 *LAP-BAND*<sup>®</sup> System units have been sold worldwide since 1993.

We also sell the *BIB*<sup>™</sup> System, which is a short-term weight loss therapy designed for use with moderately obese patients. Broadly approved around the world outside the United States, the *BIB*<sup>™</sup> System includes a silicone elastomer balloon that is filled with saline after transoral insertion into the patient's stomach to reduce stomach capacity and create an earlier sensation of fullness. The *BIB*<sup>™</sup> System is removed endoscopically within six months of being implanted, and works best when used in conjunction with a comprehensive diet and exercise program.

#### ***Other Products***

*Contigen*<sup>®</sup> is our collagen product used for treatment of urinary incontinence due to intrinsic sphincter deficiency. C. R. Bard, Inc. licenses from us the exclusive worldwide marketing and distribution rights to *Contigen*<sup>®</sup>. We also provide other collagen products for use by other medical manufacturers.

#### **International Operations**

Our international sales have represented 32.6%, 32.5% and 30.9% of our total consolidated product net sales for the years ended December 31, 2006, 2005 and 2004, respectively. Our products are sold in over 100 countries. Marketing activities are coordinated on a worldwide basis, and resident management teams provide leadership and infrastructure for customer-focused, rapid introduction of new products in the local markets.

### **Sales and Marketing**

We maintain a global marketing team, as well as regional sales and marketing organizations, in the promotion and sale of products from all of our segments. We also engage contract sales organizations to promote certain products. Our sales efforts and promotional activities are primarily aimed at eye care professionals, neurologists, plastic and reconstructive surgeons, bariatric physicians and dermatologists who use, prescribe and recommend our products. We advertise in professional journals, participate in medical meetings and utilize direct mail programs to provide descriptive product literature and scientific information to specialists in the ophthalmic, dermatological, medical aesthetics, bariatric, neurology and movement disorder fields. We have developed training modules and seminars to update physicians regarding evolving technology in our products. In 2006, we also utilized direct-to-consumer advertising for *Botox*<sup>®</sup> Cosmetic, *Botox*<sup>®</sup> for hyperhidrosis, *Restasis*<sup>®</sup>, *Refresh*<sup>®</sup> artificial tears and the *LAP-BAND*<sup>®</sup> System.

Our products are sold to drug wholesalers, independent and chain drug stores, pharmacies, commercial optical chains, opticians, mass merchandisers, food stores, hospitals, ambulatory surgery centers and medical practitioners, including ophthalmologists, neurologists, dermatologists, bariatric physicians, pediatricians, and plastic and reconstructive surgeons. As of December 31, 2006, we employed approximately 2,000 sales representatives throughout the world. We also utilize distributors for our products in smaller international markets.

U.S. sales, including manufacturing operations, represented 67.4%, 67.5% and 69.1% of our total consolidated product net sales in 2006, 2005 and 2004, respectively. Sales to Cardinal Healthcare for the years ended December 31, 2006, 2005 and 2004 were 13.0%, 14.9% and 14.1% respectively, of our total consolidated product net sales. Sales to McKesson Drug Company for the years ended December 31, 2006, 2005 and 2004 were 13.0%, 14.2% and 13.0% respectively, of our total consolidated product net sales. No other country, or single customer, generated over 10% of our total product net sales.

We sell our products directly and through independent distributors in approximately 70 countries worldwide. We supplement our marketing efforts with appearances at medical conventions, advertisements in trade journals, sales brochures, and national media. In addition, we sponsor symposia and educational programs to familiarize physicians with the leading techniques and methods of using our products.

### **Research and Development**

Our global research and development efforts currently focus on eye care, skin care, neuromodulators, medical aesthetics, obesity intervention and neurology. We also have development programs in genitourinary diseases and gastroenterology. We have a fully integrated research and development organization with in-house discovery programs, including medicinal chemistry, high throughput screening, and biological sciences. We supplement our own research and development activities with our commitment to identify and obtain new technologies through in-licensing, research collaborations, joint ventures and acquisitions.

As of December 31, 2006, we had approximately 1,200 employees involved in our research and development efforts. Our research and development expenditures for 2006, 2005 and 2004 were approximately \$1,055.5 million, \$388.3 million and \$342.9 million, respectively. Excluding in-process research and development expenditures related to company acquisitions, we have increased our annual investment in research and development by over \$243 million in the past five years. In 2004, we completed construction of a new \$75 million research and development facility in Irvine, California, which provides us with approximately 175,000 square feet of additional laboratory space. In 2005, we completed construction of a new biologics facility on our Irvine, California campus at an aggregate cost of approximately \$50 million. Both facilities are occupied and in use.

Our strategy is to develop innovative products to address unmet medical needs. Our top priorities include furthering our leadership in medical aesthetics and neuromodulators, identifying new potential compounds for sight-threatening diseases such as glaucoma, age-related macular degeneration and other retinal disorders, and developing novel therapies for dry eye, pain, gastroenterology, and genitourinary diseases. We plan to continue to build on our strong market positions in medical aesthetics, ophthalmic pharmaceuticals, medical dermatology and neurology, and to explore new therapeutic areas that are consistent with our specialty healthcare focus.

Our research and development efforts for the ophthalmic pharmaceuticals business focus primarily on new therapeutic products for retinal disease, glaucoma and dry eye. As part of our focus on diseases of the retina, we acquired Oculex Pharmaceuticals, Inc. in 2003. With this acquisition, we obtained a novel posterior segment drug delivery system for use with compounds to treat diseases, including age-related macular degeneration and other retinal disorders. We have subsequently begun Phase III studies for *Posurdex*<sup>®</sup>, dexamethasone delivered in a bioerodable implant for macular edema and retinal vein occlusion. In March 2005, we entered into an exclusive licensing agreement with Sanwa Kagaku Kenkyusho Co., Ltd. (Sanwa) to develop and commercialize *Posurdex*<sup>®</sup> for the ophthalmic specialty market in Japan. Under the terms of the agreement, Sanwa is responsible for the development and commercialization of *Posurdex*<sup>®</sup> in Japan and associated costs. Sanwa pays us a royalty based on net sales of *Posurdex*<sup>®</sup> in Japan, makes clinical development and commercialization milestone payments and reimburses us for certain expenses associated with our continuing Phase III studies outside of Japan. We are working collaboratively with Sanwa on the clinical development of *Posurdex*<sup>®</sup>, as well as overall product strategy and management. In September 2005, we entered into a multi-year alliance with Sirna Therapeutics, Inc. to develop Sirna-027, a novel RNAi-based therapeutic currently in clinical trials for age-related macular degeneration, and to discover and develop other novel RNAi-based therapeutics against select gene



targets for ophthalmic diseases.

We license memantine from Merz GmbH & Co. KGaA, and hold worldwide rights for ophthalmic use. Memantine is approved by the FDA for Alzheimer's Disease in the United States and is marketed as *Namenda*® by Forest Laboratories and as *Axura*® by Merz and as *Ebixa*® by Lundbeck in Europe. Two Phase III clinical trials have been conducted over the last five years. In January 2007, we completed the initial analysis of the data from the first of these two Phase III clinical trials of memantine for the preservation of visual function in patients with glaucoma. The use of memantine as a neuroprotective agent would be the first drug approved to prevent the loss of visual function, and potentially lead to a paradigm shift in the treatment of this important disease. To date, glaucoma treatment has focused on medications or surgery to lower intraocular pressure.

Two measures of visual function were selected in the statistical analysis plan to assess the efficacy of memantine in glaucoma. The functional measure chosen as the primary endpoint did not show a benefit of memantine in preserving visual function. In a number of analyses using the secondary functional measure, memantine demonstrated a statistically significant benefit of the high dose compared to placebo. While we are encouraged that a functional benefit of memantine was demonstrated in this secondary analysis, there are a number of challenges that remain. First, we need to complete the full assessment of the data from this complex clinical trial that contains four years of data on approximately 1,000 glaucoma patients. Once completed, we will review the data with the FDA and other regulatory agencies. Importantly, the safety and efficacy of memantine must be confirmed in the second Phase III clinical trial. Until we complete the data analysis and agency meetings, which we currently believe could take up to twelve months, we cannot assess the impact to filing and approval timing.

We continue to invest heavily in the research and development of neuromodulators, primarily *Botox*<sup>®</sup>. We are focused on both expanding the approved indications for *Botox*<sup>®</sup> and pursuing new neuromodulator-based therapeutics. This includes expanding the approved uses for *Botox*<sup>®</sup> to include treatment for spasticity, headache, brow furrow and urologic conditions, including overactive bladder. Also, we are conducting Phase II clinical trials of *Botox*<sup>®</sup> for the treatment of benign prostatic hypertrophy. In collaboration with Syntaxin, a newly formed company, whose technology was contributed by the United Kingdom government's Health Protection Agency, we are focused on engineering new neuromodulators for the treatment of severe pain. We are also continuing our investment in the areas of biologic process development and manufacturing and the next generation of neuromodulator products, and we are conducting a Phase IV study of *Botox*<sup>®</sup> for the treatment of palmar hyperhidrosis, as part of our conditions of approval for axillary hyperhidrosis by the FDA .

In connection with our obesity intervention products, we are planning to conduct clinical trials of the *BIB*<sup>tm</sup> System, which is currently approved in Europe, with the goal of obtaining approval in the United States. We anticipate beginning those trials in 2007.

We are also working to leverage our technologies in therapeutic areas outside of our current specialties, such as our Phase II clinical trials for the use of alpha agonists for the treatment of neuropathic pain. Additionally, we have novel proton pump inhibitors which reduce excess stomach acid secretion and have a longer half life than current standards of care. Our intention is to out-license these compounds to a large pharmaceutical company with a large general practitioner sales force.

In December 2002, we entered into a strategic research collaboration and license agreement with ExonHit Therapeutics. The goals of this collaboration are to identify new molecular targets based on ExonHit Therapeutics' gene profiling *DATAS*<sup>tm</sup> technology and to work collaboratively developing unique compounds and commercial products based on these targets. Our strategic alliance with ExonHit Therapeutics provides us with the rights to compounds developed in the fields of neurodegenerative disease, pain and ophthalmology.

The continuing introduction of new products supplied by our research and development efforts and in-licensing opportunities are critical to our success. There are intrinsic uncertainties associated with research and development efforts and the regulatory process. We cannot assure you that any of the research projects or pending drug marketing approval applications will result in new products that we can commercialize. Delays or failures in one or more significant research projects and pending drug marketing approval applications could have a material adverse affect on our future operations.

### **Manufacturing**

We manufacture the majority of our commercial products in our own plants located in Arklow, Ireland; San José, Costa Rica; Annecy, France;

Fremont, California; Warsaw, Poland; Waco, Texas; Westport, Ireland; and Guarulhos, Brazil. We maintain sufficient manufacturing capacity at these facilities to support forecasted demand as well as a modest safety margin of additional capacity to meet peaks of demand and sales growth in excess of expectations. We increase our capacity as required in anticipation of future sales increases. In the event of a very large or very rapid unforeseen increase in market demand for a specific product or technology, supply of that product or technology could be negatively impacted until additional capacity is brought on line. Third parties manufacture a small number of commercial products for us. However, the revenues from these products are not material to our operating results.

We are vertically integrated into the production of plastic parts and produce our own bottles, tips and caps for use in the manufacture of our ophthalmic solutions. Additionally, we ferment, purify and characterize the botulinum toxin used in our product *Botox*<sup>®</sup>. With these two exceptions, we purchase all other significant raw materials from qualified domestic and international sources. Where practical, we maintain more than one supplier for each material, and we have an ongoing alternate sourcing endeavor that identifies additional sources of key raw materials. In some cases, however, most notably with active pharmaceutical ingredients, we are a niche purchaser of specialty chemicals, which, in certain cases, are sole sourced. These sources are identified in filings with regulatory agencies, including the FDA, and cannot be changed without prior regulatory approval. In these cases, we maintain inventories of the raw material itself and precursor intermediates to mitigate the risk of interrupted supply. A lengthy interruption of the supply of one of these materials could adversely affect our ability to manufacture and supply commercial product. A small number of the raw materials required to manufacture certain of our products are derived from biological sources which could be subject to contamination and recall by their suppliers. We use multiple lots of these raw materials at any one time in order to mitigate such risks. However, a shortage, contamination or recall of these products could disrupt our ability to maintain an uninterrupted commercial supply of our finished goods.

Manufacturing facilities producing medical devices intended for distribution in the United States and internationally are subject to regulation and periodic review by the FDA, international regulatory authorities, and European notified bodies for certain of our medical devices. All of our facilities are currently approved by the FDA, the relevant notified bodies and other regulatory authorities to manufacture medical devices for distribution in the United States and international markets.

### **Competition**

The pharmaceutical and medical device industries are highly competitive and require an ongoing, extensive search for technological innovation. They also require, among other things, the ability to effectively discover, develop, test and obtain regulatory approvals for products, as well as the ability to effectively commercialize, market and promote approved products, including communicating the effectiveness, safety and value of products to actual and prospective customers and medical professionals. Numerous companies are engaged in the development, manufacture and marketing of health care products competitive with those that we manufacture and develop. Many of our competitors have greater resources than we have. This enables them, among other things, to make greater research and development investments and spread their research and development costs, as well as their marketing and promotion costs, over a broader revenue base. Our competitors may also have more experience and expertise in obtaining marketing approvals from the FDA and other regulatory authorities. In addition to product development, testing, approval and promotion, other competitive factors in the pharmaceutical and medical device industries include industry consolidation, product quality and price, product technology, reputation, customer service and access to technical information. We believe that our products principally compete on the basis of quality, product design, management's knowledge of and sensitivity to market demands, an experienced sales force, physicians and surgeons' familiarity with our products and brand names, regional warranty programs, and our ability to identify and develop or license patented products embodying new technologies.

#### ***Specialty Pharmaceuticals Segment***

*Eye Care Pharmaceuticals.* Our major eye care competitors include Alcon Laboratories, Inc., Bausch & Lomb, Pfizer, Novartis Ophthalmics and Merck & Co., Inc. For our eye care products to be successful, we must be able to manufacture and effectively market those products and persuade a sufficient number of eye care professionals to use or continue to use our current products and the new products we may introduce. Glaucoma must be treated over an extended period

and doctors may be reluctant to switch a patient to a new treatment if the patient's current treatment for glaucoma remains effective.

In addition, we also face competition from generic drug manufacturers in the United States and internationally. For instance, Falcon Pharmaceuticals, Ltd., an affiliate of Alcon Laboratories, Inc., attempted to obtain FDA approval for and to launch a brimonidine product to compete with our *Alphagan*<sup>®</sup> *P* product. However, pursuant to a March 2006 settlement with Alcon, Alcon agreed not to sell, offer for sale or distribute its brimonidine product until September 30, 2009, or earlier if specified market conditions occur. The primary market condition will have

occurred if the extent to which prescriptions of *Alphagan*<sup>®</sup> *P* have been converted to other brimonidine-containing products we market has increased to a specified threshold. In addition, Apotex, Inc. attempted to obtain FDA approval for and to launch a generic form of *Acular*<sup>®</sup>. Pursuant to a federal court ruling in June 2006, Apotex is barred from obtaining approval before our *Acular*<sup>®</sup> patent expires in 2009. See Item 3 of Part I of this report, Legal Proceedings and Note 12, Commitments and Contingencies, in the notes to the consolidated financial statements listed under Item 15 of Part IV of this report, Exhibits and Financial Statement Schedules, for information concerning our current litigation.

*Neuromodulators.* With respect to neuromodulators, until December 2000, *Botox*<sup>®</sup> was the only neuromodulator approved by the FDA. At that time, the FDA approved *Myobloc*<sup>®</sup>, a neuromodulator formerly marketed by Elan Pharmaceuticals and now marketed by Solstice Neurosciences Inc. Beaufour Ipsen Ltd. is seeking FDA approval of its *Dysport*<sup>®</sup> neuromodulator for certain therapeutic indications, and Medicis Pharmaceutical Corporation, its licensee for the United States, Canada and Japan, is seeking approval of *Reloxin*<sup>®</sup> for cosmetic indications. Beaufour Ipsen has marketed *Dysport*<sup>®</sup> in Europe since 1991, prior to our European commercialization of *Botox*<sup>®</sup> in 1992. In June 2006, Beaufour Ipsen received the marketing authorization for a cosmetic indication for *Dysport*<sup>®</sup> in Germany. In 2007, Beaufour Ipsen granted an exclusive development and marketing license for *Dysport*<sup>®</sup> to Galderma, a joint venture between Nestle and L'Oréal, in the European Union, Russia, Eastern Europe and the Middle East, and first rights of negotiation for other countries around the world, except the United States, Canada and Japan. Beaufour Ipsen is also seeking approval for *Reloxin*<sup>®</sup> for cosmetic indications across the European Union. Also, Mentor Corporation is conducting clinical trials for a competing neuromodulator in the United States. In addition, we are aware of competing neuromodulators currently being developed and commercialized in Asia, Europe, South America and other markets. A Chinese entity received



approval to market a botulinum toxin in China in 1997, and we believe that it has launched or is planning to launch its botulinum toxin product in other lightly regulated markets in Asia, South America and Central America. These lightly regulated markets may not require adherence to the FDA's current Good Manufacturing Practice regulations, or cGMPs, or the regulatory requirements of the European Medical Evaluation Agency or other regulatory agencies in countries that are members of the Organization for Economic Cooperation and Development. Therefore, companies operating in these markets may be able to produce products at a lower cost than we can. In addition, Merz received approval for *Xeomin*<sup>®</sup> in Germany and launched its product in July 2005, received approval in Mexico in 2006 and is pursuing additional approvals in the European Union and Latin America. A Korean botulinum toxin product, *Neuronox*<sup>®</sup>, was approved for sale in Korea in June 2006. The company, Medy-Tox Inc., received exportation approval from Korean authorities in early 2005. In February 2007, Q-Med announced a worldwide license for *Neuronox*<sup>®</sup>, with the exception of certain countries in Asia where Medy-Tox may retain the marketing rights.

*Skin Care Product Line.* Our skin care business competes against a number of companies, including among others, Dermik, a division of Sanofi-Aventis, Galderma, Medicis, Stiefel, Novartis, Schering-Plough Corporation and Johnson & Johnson, most of which have greater resources than us.

#### ***Medical Devices Segment***

*Breast Aesthetics.* We compete in the U.S. breast implant market with Mentor Corporation. Mentor announced that, like us, it received FDA approval in November 2006 to sell its silicone breast implants. The conditions under which Mentor is allowed to market its silicone breast implants in the United States are similar to ours, including indications for use and the requirement to conduct post-marketing studies. If patients or physicians prefer Mentor's breast implant products to ours or perceive that Mentor's breast implant products are safer than ours, our sales of breast implants could materially suffer. We are aware of several

companies conducting clinical studies of breast implant products in the United States.

Internationally, we compete with several manufacturers, including Mentor Corporation, Silimed, Medicor Corporation, Poly Implant Protheses, Nagor, Laboratories Sebbin, and LPI.

*Facial Aesthetics.* Our facial products compete in the dermatology and plastic surgery markets with other hyaluronic acid products, substantially different treatments, such as laser treatments, chemical peels, fat injections, gelatin- or cadaver-based collagen products, and botulinum toxin-based products, as well as other polymer-based injectibles. In addition, several companies are engaged in research and development activities examining the use of collagen, hyaluronic acids and other biomaterials for the correction of soft tissue defects. Internationally, we

compete with products such as *Restylane*<sup>®</sup>, *Restylane*<sup>®</sup> Fine Lines, and *Perlane*<sup>™</sup> (all manufactured by Q-Med A.B.). Since the first quarter of 2004, we have competed in the U.S. dermal filler market with *Restylane*<sup>®</sup>, which is distributed by Medicis. Also, in 2006, *Radiesse*<sup>®</sup>, a filler from BioForm Medical, Inc., received approval in the United States.

*Obesity Intervention.* No gastric bands other than our *LAP-BAND*<sup>®</sup> System are commercially available in the United States, and we are currently aware of only one other company conducting U.S. clinical studies of gastric bands. This company, Ethicon Endo-Surgery, Inc., a Johnson & Johnson company, announced an early 2007 premarket filing target for FDA approval of its gastric band product, SAGB Quick Close (Swedish Adjustable Gastric Band), which will compete against our *LAP-BAND*<sup>®</sup> System upon entry to the U.S. market. Outside the United States, the *LAP-BAND*<sup>®</sup> System competes primarily with the Swedish Adjustable Gastric Band and the Heliogast Band (manufactured by Helioscopie, S.A., France). There are at least two other gastric bands on the market internationally. The *LAP-BAND*<sup>®</sup> System also competes with surgical obesity procedures, including gastric bypass, vertical banded gastroplasty, and biliopancreatic diversion. No intragastric balloons for the treatment of obesity are commercially available in the United States, and we are currently aware of only one other company outside the United States, Helioscopie, which recently launched its intragastric balloon, the Heliosphere. We are not aware of any published clinical studies that support this device's effectiveness.

## **Government Regulation**

### ***Specialty Pharmaceuticals Segment***

Drugs and biologics are subject to regulation by the FDA, state agencies and, in varying degrees, by foreign health agencies. Pharmaceutical products and biologics are subject to extensive pre- and post-market regulation by the FDA, including regulations that govern the testing,

manufacturing, safety, efficacy, labeling, storage, record keeping, advertising and promotion of the products under the Federal Food, Drug, and Cosmetic Act, or FDCA, with respect to drugs and the Public Health Services Act with respect to biologics, and by comparable agencies in foreign countries. Failure to comply with applicable FDA or other requirements may result in civil or criminal penalties, recall or seizure of products, partial or total suspension of production or withdrawal of a product from the market.

The process required by the FDA before a new drug or biologic may be marketed in the United States generally involves the following: completion of preclinical laboratory and animal testing; submission of an Investigational New Drug Application, or IND, which must become effective before clinical trials may begin; and performance of adequate and well controlled human clinical trials to establish the safety and efficacy of the proposed drug or biologic for its intended use. Clinical trials are typically conducted in three sequential phases, which may overlap, and must satisfy extensive Good Clinical Practice regulations and regulations for informed consent. Further, an independent institutional review board (IRB) for each medical center proposing to conduct the clinical trial must review and approve the plan for any clinical trial before it commences at that center and must monitor the study until completed. The FDA, the IRB, or the study sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk.

Approval by the FDA of a New Drug Application, or NDA, is required prior to marketing a new drug, and approval of a Biologics License Application, or BLA, is required before a biologic may be legally marketed in the United States. To satisfy the criteria for approval, an NDA or BLA must demonstrate the safety and efficacy of the product based on results of product development, preclinical studies and the three phases of clinical trials. Both NDAs and BLAs must also contain extensive manufacturing information, and the applicant must pass an FDA pre-approval inspection of the manufacturing facilities at which the drug or biologic is produced to assess

compliance with the cGMP regulations prior to commercialization. Satisfaction of FDA pre-market approval requirements typically takes several years and the actual time required may vary substantially based on the type, complexity and novelty of the product, and we cannot be certain that any approvals for our products will be granted on a timely basis, or at all.

Once approved, the FDA may withdraw product approval if compliance with pre- and post-market regulatory standards is not maintained or if safety problems occur after the product reaches the marketplace. In addition, the FDA may require post-marketing clinical studies, known as Phase IV studies, and surveillance programs to monitor the effect of approved products. The FDA may limit further marketing of the product based on the results of these

post-market studies and programs. Drugs and biologics may be marketed only for the approved indications and in accordance with the provisions of the approved label. Further, any modifications to the drug or biologic, including changes in indications, labeling, or manufacturing processes or facilities, may require the submission of a new or supplemental NDA or BLA, which may require that we develop additional data or conduct additional preclinical studies and clinical trials.

Any products manufactured or distributed by us or our collaborators pursuant to FDA approvals are also subject to continuing regulation by the FDA, including recordkeeping requirements and reporting of adverse experiences associated with the drug. Drug and biologic manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with ongoing regulatory requirements, including cGMPs, which regulate all aspects of the manufacturing process and impose certain procedural and documentation requirements. Failure to comply with the statutory and legal requirements can subject a manufacturer to possible legal or regulatory action, including fines and civil penalties, suspension or delay in the issuance of approvals, seizure or recall of products, and withdrawal of approvals, any one or more of which could have a material adverse effect upon us.

The FDA imposes a number of complex regulatory requirements on entities that advertise and promote pharmaceuticals and biologics, including, but not limited to, standards and regulations for direct-to-consumer advertising, off-label promotion, industry sponsored scientific and educational activities, and promotional activities involving the Internet. A manufacturer can make only those claims relating to safety and efficacy that are approved by the FDA. The FDA has very broad enforcement authority under the FDCA, and failure to abide by these regulations can result in penalties, including the issuance of a warning letter directing us to correct deviations from FDA standards, a requirement that future

advertising and promotional materials be pre-cleared by the FDA, and state and federal civil and criminal investigations and prosecutions. Physicians may prescribe (although we are not permitted to promote) legally available drugs and biologics for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. Such off-label uses are common across medical specialties.

Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, impose stringent restrictions on manufacturers' communications regarding off-label use.

We are also subject to various laws and regulations regarding laboratory practices, the experimental use of animals, and the use and disposal of hazardous or potentially hazardous substances in connection with our research. In each of these areas, as above, the FDA has broad regulatory and enforcement powers, including the ability to levy fines and civil penalties, suspend or delay the issuance of approvals, seize or recall products, and withdraw approvals, any one or more of which could have a material adverse effect upon us.

Internationally, the regulation of drugs is also complex. In Europe, our products are subject to extensive regulatory requirements. As in the United States, the marketing of medicinal products has for many years been subject to the granting of marketing authorizations by medicine agencies. Particular emphasis is also being placed on more sophisticated and faster procedures for reporting adverse events to the competent authorities. The European Union procedures for the authorization of medicinal products were amended in May 2004 and are now effective. The amended procedures are intended to improve the efficiency of operation of both the mutual recognition and centralized procedures. Additionally, new rules have been introduced or are under discussion in several areas, including the harmonization of clinical research laws and the law relating to orphan drugs and orphan indications. Outside the United States, reimbursement pricing is typically regulated by

government agencies.

The total cost of providing health care services has been and will continue to be subject to review by governmental agencies and legislative bodies in the major world markets, including the United States, which are faced with significant pressure to lower health care costs. The Medicare Prescription Drug Modernization Act of 2003 imposed certain reimbursement restrictions on our products in the United States. Additionally, Medicare Part D and proposed federal and state legislation may result in additional reimbursement and rebate obligations. These reimbursement restrictions or other price reductions or controls could materially and adversely affect our revenues and financial condition. Additionally, price reductions and rebates have recently been mandated in several European countries, principally Germany, Italy, Spain and the United Kingdom. Certain products are also no longer eligible for reimbursement in France, Italy and Germany. Reference pricing is used in several markets around the



world to reduce prices. Furthermore, parallel trade within the European Union, whereby products flow from relatively low-priced to high-priced markets, has been increasing.

We cannot predict the likelihood or pace of any significant regulatory or legislative action in these areas, nor can we predict whether or in what form health care legislation being formulated by various governments will be passed. Medicare reimbursement rates are subject to change at any time. We also cannot predict with precision what effect such governmental measures would have if they were ultimately enacted into law. However, in general, we believe that such legislative activity will likely continue. If adopted, such measures can be expected to have an impact on our business.

#### ***Medical Devices Segment***

Medical devices are subject to regulation by the FDA, state agencies and, in varying degrees, by foreign government health agencies. FDA regulations, as well as various U.S. federal and state laws, govern the development, clinical testing, manufacturing, labeling, record keeping, and marketing of medical device products. The majority of our medical device product candidates, including our breast implants, must undergo rigorous clinical testing and an extensive government regulatory approval process prior to sale in the United States and other countries. The lengthy process of clinical development and seeking required approvals, and the continuing need for compliance with applicable laws and regulations, require the expenditure of substantial resources. Regulatory approval, when and if obtained, may be limited in scope, and may significantly limit the indicated uses for which a product may be marketed. Approved products and their manufacturers are subject to ongoing review, and discovery of previously unknown problems with products may result in restrictions on their manufacture, sale, or use, or their withdrawal from the market.

Our breast implants and obesity products are medical devices intended for human use and are subject to extensive regulation by the FDA in the

United States. Unless an exemption applies, each medical device we market in the United States must have a 510(k) clearance or a Premarket Approval (PMA) application in accordance with the FDCA. The FDA classifies medical devices into one of three classes, depending on the degree of risk associated with each medical device and the extent of controls that are needed to ensure safety and effectiveness. Devices deemed to pose a lower risk are placed in either Class I or Class II, which requires the manufacturer to submit to the FDA a premarket notification under Section 510(k) of the FDCA requesting permission for commercial distribution. This process is known as 510(k) clearance. Some low risk devices are exempted from this requirement. Devices deemed by the FDA to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices, or a device deemed to be not substantially equivalent to a previously cleared 510(k) device, are placed in Class III. In general, a Class III device cannot be marketed in the United States unless the FDA approves the device after submission of a PMA application. The majority of our medical device products, including our breast implants, are regulated as Class III medical devices.

When we are required to obtain a 510(k) clearance for a device we wish to market, we must submit a premarket notification to the FDA demonstrating that the device is substantially equivalent to a previously cleared 510(k) device or a device that was in commercial distribution before May 28, 1976 for which the FDA has not yet called for the submission of PMA applications. By regulation, the FDA is required to respond to a 510(k) premarket notification within 90 days of submission of the notification. As a practical matter, clearance can take significantly longer. If the FDA determines that the device, or its intended use, is not substantially equivalent to a previously-cleared device or use, the FDA will place the device, or the particular use of the device, into Class III. After a device receives 510(k) clearance for a specific intended use, any modification that could significantly affect its safety or efficacy, or that would constitute a major change in its intended use, design or manufacture, will require a new 510(k) clearance or could require PMA approval. The FDA requires each

manufacturer to make this determination initially, but the FDA can review any such decision and can disagree with a manufacturer's determination. If the FDA disagrees with a manufacturer's determination that a new clearance or approval is not required for a particular modification, the FDA can require the manufacturer to cease marketing and/or recall the modified device until 510(k) clearance or premarket approval is obtained.

A PMA application must be submitted if the device cannot be cleared through the 510(k) process. The PMA process is much more demanding than the 510(k) clearance process. A PMA application must be supported by

extensive information, including data from preclinical and clinical trials, sufficient to demonstrate to the FDA's satisfaction that the device candidate is safe and effective for its intended use. The FDA, by statute and regulation, has 180 days to review an accepted premarket approval application, although the review generally occurs over a significantly longer period of time, and can take up to several years. During this review period, the FDA may request additional information or clarification of information already provided. Also during the review period, an advisory panel of experts from outside the FDA may be convened to review and evaluate the application and provide recommendations to the FDA as to the approvability of the device. New PMA applications or supplemental PMA applications are required for significant modifications to the manufacturing process, labeling and design of a medical device that is approved through the PMA process. PMA supplements often require submission of the same type of information as an initial PMA, except that the supplement is limited to information needed to support any changes from the device covered by the original PMA application, and may not require as extensive clinical data or the convening of an advisory panel.

A clinical trial is almost always required to support a PMA application and is sometimes required for a 510(k) premarket notification. These trials generally require submission of an application for an investigational device exemption, or IDE, to the FDA. The IDE application must be supported by appropriate data, such as animal and laboratory testing results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. Clinical trials for a significant risk device may begin once the IDE application is approved by the FDA and the IRB overseeing the clinical trial. If the product is deemed a non-significant risk device, only approval from the IRB overseeing the clinical trial is required. We, the FDA or the IRB at each site at which a clinical trial is being performed may suspend a clinical trial at any time for various reasons, including a belief that the

study subjects are being exposed to an unacceptable health risk. The results of clinical testing may not be sufficient to obtain approval of the product.

After a device is placed on the market, numerous regulatory requirements apply. These include:

Quality System Regulation, which requires manufacturers to follow design, testing, control documentation and other quality assurance procedures during the manufacturing process;

Labeling regulations, which prohibit the promotion of products for unapproved or off-label uses and impose other restrictions on labeling; and

Medical device reporting, or MDR, regulations, which require that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to recur.

Compliance with regulatory requirements is assured through periodic, unannounced facility inspections by the FDA and other regulatory authorities, and these inspections may include the manufacturing facilities of our subcontractors. Failure to comply with applicable regulatory requirements can result in enforcement action by the FDA, which may include any of the following sanctions: Warning Letters or untitled letters; fines, injunctions and civil penalties; recall or seizure of our products; operating restrictions, partial suspension or total shutdown of production; refusing our request for 510(k) clearance or PMA approval of new products; withdrawing 510(k) clearance or PMAs that are already granted; and criminal prosecution.

Products that are marketed in the European Union, or EU, must comply with the requirements of the Medical Device Directive, or MDD, as implemented into the national legislation of the EU member states. The MDD, as implemented, provides for a regulatory regime with respect to the design, manufacture, clinical trials, labeling and adverse event reporting for medical devices to

ensure that medical devices marketed in the EU are safe and effective for their intended uses. Medical devices that comply with the MDD, as implemented, are entitled to bear a CE marking and may be marketed in the EU. Medical device laws and regulations similar to those described above are also in effect in many of the other countries to which we export our products. These range from comprehensive device approval requirements for some or all of our medical device products to requests for product data or certifications. Failure to comply with these domestic and international regulatory requirements could affect our ability to market and sell our products in these countries.

### ***Other Regulations***

We are subject to federal, state, local and foreign environmental laws and regulations, including the U.S. Occupational Safety and Health Act, the U.S. Toxic Substances Control Act, the U.S. Resource Conservation and Recovery Act, Superfund Amendments and Reauthorization Act, Comprehensive Environmental Response, Compensation and Liability Act and other current and potential future federal, state, or local regulations. Our manufacturing and research and development activities involve the controlled use of hazardous materials, chemicals, and biological materials, which require compliance with various laws and regulations regarding the use, storage, and disposal of such materials. We cannot assure you, however, that environmental problems relating to properties owned or operated by us will not develop in the future, and we cannot predict whether any such problems, if they were to develop, could require significant expenditures on our part. In addition, we are unable to predict what legislation or regulations may be adopted or enacted in the future with respect to environmental protection and waste disposal. Additionally, we may be subject either directly or by contract to federal and state laws pertaining to the privacy and security of personal health information.

We are also subject to various federal and state laws pertaining to health care fraud and abuse. The federal Anti-Kickback Statute makes it illegal to solicit, offer, receive or pay any remuneration, directly or indirectly, in cash or in kind, in exchange for, or to induce, the referral of business, including the purchase or prescription of a particular product, for which payment may be made under government health care programs such as Medicare and Medicaid. The U.S. federal government has published regulations that identify safe harbors or exemptions for certain practices from enforcement actions under the Anti-Kickback Statute. We seek to comply with the safe harbors where possible. Due to the breadth of the statutory provisions and in the absence of guidance in the form of regulations or court decisions addressing some of our practices,

it is possible that our practices might be challenged under the Anti-Kickback Statute or similar laws. The federal False Claims Act prohibits anyone from knowingly and willingly presenting, or causing to be presented for payment to third party payors (including Medicare and Medicaid) claims for reimbursed products or services that are false or fraudulent, claims for items or services not provided as claimed, or claims for medically unnecessary items or services. The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, prohibits executing a scheme to defraud any healthcare benefit program or making false statements relating to health care matters. In addition, many states have adopted laws similar to the federal fraud and abuse laws discussed above, which, in some cases, apply to all payors whether governmental or private. Our activities, particularly those relating to the sale and marketing of our products, may be subject to scrutiny under these laws. Violations of fraud and abuse laws may be punishable by criminal and/or civil sanctions, including fines and civil monetary penalties, as well as the possibility of exclusion from federal health care programs (including Medicare and Medicaid).

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

We own, or are licensed under, numerous U.S. and foreign patents relating to our products, product uses and manufacturing processes. We believe that our patents and licenses are important to all segments of our business.

With the exception of the U.S. and European patents relating to *Lumigan*<sup>®</sup> and *Alphagan*<sup>®</sup> *P*, and the U.S. patents relating to *Restasis*<sup>®</sup>, *Acular*<sup>®</sup> and *Zymar*<sup>®</sup>, no one patent or license is currently of material importance in relation to our overall sales for our specialty pharmaceuticals segment. The U.S. compound and ophthalmic use patents covering *Lumigan*<sup>®</sup> currently expire in 2015. The European patent covering *Lumigan*<sup>®</sup> expires in various countries between 2013 and 2017. The U.S. patent covering the commercial formulation of *Acular*<sup>®</sup> expires in 2009 and in 2008 in Europe. The U.S. patents covering the commercial formulation of *Alphagan*<sup>®</sup> *P* expire in 2012 and 2021 and in 2009 in Europe, with corresponding



patents pending. The U.S. patents covering *Restasis*<sup>®</sup> expire in 2009 and 2014. *Zymar*<sup>®</sup> s various U.S. patents expire in mid-2010, late 2015 and late 2019.

Our success depends in part on our ability to obtain patents or rights to patents, protect trade secrets and other proprietary technologies and processes, operate without infringing upon the proprietary rights of others, and prevent others from infringing on our patents, trademarks, service marks and other intellectual property rights. Upon the expiration or loss of patent protection for a product, we can lose a significant portion of sales of that product in a very short period of time as other companies manufacture generic forms of our previously protected product at lower cost, without having had to incur significant research and development costs in formulating the product. In

addition, the issuance of a patent is not conclusive as to its validity or as to the enforceable scope of the claims of the patent. It is impossible to anticipate the breadth or degree of protection that any such patents will afford, or that any such patents will not be successfully challenged in the future. Accordingly, our patents may not prevent other companies from developing substantially identical products. Hence, if our patent applications are not approved or, even if approved, such patents are circumvented, our ability to competitively exploit our patented products and technologies may be significantly reduced. Also, such patents may or may not provide competitive advantages for their respective products, in which case our ability to commercially exploit these products may be diminished.

Third parties may challenge, invalidate or circumvent our patents and patent applications relating to our products, product candidates and technologies. Challenges may result in potentially significant harm to our business. The cost of responding to these challenges and the inherent costs to defend the validity of our patents, including the prosecution of infringements and the related litigation, can require a substantial commitment of our management's time, be costly and can preclude or delay the commercialization of products. See Item 3 of Part I of this report, Legal Proceedings and Note 12, Commitments and Contingencies, in the notes to the consolidated financial statements listed under Item 15 of Part IV of this report, Exhibits and Financial Statement Schedules, for information concerning our current intellectual property litigation.

From time to time, we may need to obtain licenses to patents and other proprietary rights held by third parties to develop, manufacture and market our products. If we are unable to timely obtain these licenses on commercially reasonable terms, our ability to commercially exploit such products may be inhibited or prevented. See Item 1A of Part I of this report, Risk Factors.

We market our products under various trademarks, for which we have both registered and unregistered trademark protection in the United

States and certain countries outside the United States. We consider these trademarks to be valuable because of their contribution to the market identification of our products. Any failure to adequately protect our rights in our various trademarks and service marks from infringement, could result in a loss of their value to us. If the marks we use are found to infringe upon the trademark or service mark of another company, we could be forced to stop using those marks and, as a result, we could lose the value of those marks and could be liable for damages caused by an infringement. In addition to intellectual property protections afforded to trademarks, service marks and proprietary know-how by the various countries in which our proprietary products are sold, we seek to protect our trademarks, service marks and proprietary know-how through confidentiality agreements with third parties, including our partners, customers, employees and consultants. These agreements may be breached or become unenforceable, and we may not have adequate remedies for any such breach. It is also possible that our trade secrets will become known or independently developed by our competitors, resulting in increased competition for our products.

In addition, we are currently engaged in various collaborative ventures for the development, manufacturing, and distribution of current and new products. These projects include the following:

We have entered into an exclusive licensing agreement with Kyorin Pharmaceutical Co., Ltd., under which Kyorin became responsible for the development and commercialization of *Alphagan*<sup>®</sup> and *Alphagan*<sup>®</sup> P in Japan. Kyorin subsequently sub-licensed its rights under the agreement to Senju Pharmaceutical Co., Ltd. Under the licensing agreement, Senju incurs associated costs, makes clinical development and commercialization milestone payments, and makes royalty-based payments on product sales. We are working collaboratively with Senju on overall product strategy and management.

We have entered into an exclusive licensing agreement with Senju Pharmaceutical Co.,

Ltd., under which Senju became responsible for the development and commercialization of *Lumigan*<sup>®</sup> in Japan's ophthalmic specialty area. Senju incurs associated costs, makes development and commercialization milestone payments and makes royalty-based payments on product sales. We are working collaboratively with Senju on overall product strategy and management.

We have licensed from Novartis the worldwide, excluding Japan, rights for technology, patents and products relating to the topical ophthalmic use of cyclosporine A, the active ingredient in *Restasis*<sup>®</sup>. In April 2005, we entered into a royalty buy-out agreement with Novartis related to *Restasis*<sup>®</sup> and agreed to pay \$110 million to

Novartis. As a result of the buy-out agreement, we no longer pay royalties to Novartis based on sales of *Restasis*.

We have been the distributor and licensee for Genzyme Corporation's *Hylaform*<sup>®</sup> products since 1999, including *Hylaform*<sup>®</sup> Plus and *Hylaform*<sup>®</sup> FineLine. In December 2004, we entered into an amended and restated agreement with Genzyme Corporation for exclusive U.S. development and distribution rights of *Captique*<sup>™</sup>, a non-animal based hyaluronic acid-based dermal filler. We purchase these products from Genzyme Corporation and pay royalties based on sales.

Through Inamed, in June 2004, we entered into a settlement agreement with Ethicon Endo-Surgery, Inc. pursuant to which, among other terms, we were granted a worldwide, royalty-bearing, non-exclusive license with respect to a portfolio of U.S. and international patents applicable to adjustable gastric bands.

We are also a party to license agreements allowing other companies to manufacture products using some of our technology in exchange for royalties and other compensation or benefits. Although we believe our patents and patent rights are valuable, our technical knowledge with respect to manufacturing processes, materials, and product design are also valuable.

### **Environmental Matters**

We are subject to federal, state, local and foreign environmental laws and regulations. We believe that our operations comply in all material respects with applicable environmental laws and regulations in each country where we have a business presence. Although we continue to make capital expenditures for environmental protection, we do not anticipate any significant expenditures in order to comply with such laws and regulations that would have a material impact on our earnings or competitive position. We are not aware of any pending litigation or significant financial obligations arising from current or past environmental practices that are likely to have a

material adverse effect on our financial position. We cannot assure you, however, that environmental problems relating to properties owned or operated by us will not develop in the future, and we cannot predict whether any such problems, if they were to develop, could require significant expenditures on our part. In addition, we are unable to predict what legislation or regulations may be adopted or enacted in the future with respect to environmental protection and waste disposal.

### **Seasonality**

Our business, both taken as a whole and by our business segments, is not materially affected by seasonal factors, although we have noticed an historical trend with respect to sales of our *Botox*<sup>®</sup> product. Specifically, sales of *Botox*<sup>®</sup> have tended to be lowest during the first fiscal quarter, with sales during the second and third fiscal quarters being comparable and marginally higher than sales during the first fiscal quarter. *Botox*<sup>®</sup> sales during the fourth fiscal quarter have tended to be the highest due to patients obtaining their final therapeutic treatment at the end of the year, presumably to fully utilize deductibles and to receive additional cosmetic treatments prior to the holiday season.

### **Third Party Coverage and Reimbursement**

Health care providers generally rely on third-party payors, including governmental payors such as Medicare and Medicaid, and private insurance carriers, to adequately cover and reimburse the cost of pharmaceuticals and medical devices. Such third-party payors are increasingly challenging the price of medical products and services and instituting cost containment measures to control or significantly influence the purchase of medical products and services. The market for our products therefore is influenced by third-party payors policies. This includes the placement of our pharmaceutical products on drug formularies or lists of medications.

Purchases of aesthetic products and procedures using those products generally are not covered by most third-party payors, and patients incur out-of-pocket costs for such products and

associated procedures. This includes breast  
aesthetics products for augmentation and facial  
aesthetics products. Since 1998, however,  
U.S. federal law has mandated that group health  
plans, insurance companies and health  
maintenance organizations offering mastectomy  
coverage must also provide coverage for  
reconstructive surgery following a

mastectomy, which includes coverage for breast implants. Outside the United States, reimbursement for breast implants used in reconstructive surgery following a mastectomy may be available, but the programs vary on a country by country basis.

Furthermore, treatments for obesity alone may not be covered by third-party payors. In February 2006, Medicare began covering certain designated bariatric surgical services, including gastric bypass surgery and procedures using the *LAP-BAND*<sup>®</sup> System, for Medicare patients with a body mass index equal to or greater than 35, who have at least one co-morbidity and have been previously unsuccessful with the medical treatment of obesity. However, the policy reiterates that treatments for obesity alone are not covered, because such treatments are not considered reasonable and necessary. While Medicare policies are sometimes adopted by other third-party payors, other governmental and private insurance coverage currently varies by carrier and geographic location, and we actively work with major insurance carriers to obtain reimbursement coverage for procedures using our *LAP-BAND*<sup>®</sup> System product. For instance, the Technology Evaluation Center of the Blue Cross/Blue Shield National Association provided a positive assessment of the *LAP-BAND*<sup>®</sup> System, an important step in providing private payor reimbursement for the procedure.

Outside the United States, reimbursement programs vary on a country by country basis. In some countries, both the procedure and product are fully reimbursed by the government healthcare systems for all citizens who need it, and there is no limit on the number of procedures that can be performed. In other countries, there is complete reimbursement but the number of procedures that can be performed at each hospital is limited either by the hospital's overall budget or by the budget for the type of product.

In the United States, there has been and continues to be a number of legislative initiatives to contain health care coverage and reimbursement by governmental and other payors. For example, the



Medicare Prescription Drug, Improvement, and Modernization Act of 2003 implemented a new Part D prescription drug benefit under which Medicare beneficiaries can purchase certain prescription drugs at discounted prices from private sector entities, or Part D plan sponsors. Currently, drug manufacturers negotiate directly with Part D plan sponsors to determine whether their drugs will be listed on a Part D formulary and the prices at which such drugs will be listed. Industry competition to be included in formularies maintained by both private payors and Part D plans can result in downward pricing pressures on pharmaceutical companies. Although certain lawmakers have suggested recently that the federal government may be granted the authority to negotiate the prices of drugs included on Part D formularies, at this time the federal government does not have such authority. There has also been an increased emphasis in the marketplace on the delivery of more cost-effective medical devices as well as a number of federal and state proposals to limit payments by governmental payors for medical devices and the procedures in which medical devices are used.

### **Breast Implant Replacement Programs**

We conduct our product development, manufacturing, marketing, and service and support activities with careful regard for the consequences to patients. As with any medical device manufacturer, however, we receive communications from surgeons or patients with respect to various products claiming the products were defective, lost volume, or have resulted in injury to patients. In the event of a loss of shell integrity resulting in breast implant rupture or deflation that requires surgical intervention with respect to our breast implant products sold and implanted in the United States, in most cases our *ConfidencePlus*<sup>™</sup> programs provide lifetime product replacement and some financial assistance for surgical procedures required within ten years of implantation. Breast implants sold and implanted elsewhere are subject to a similar program. We do not warrant any level of aesthetic result and, as required by government regulation, make extensive disclosure concerning the risks of our products and implantation surgery.

**Employee Relations**

At December 31, 2006, we employed approximately 6,772 persons throughout the world, including approximately 3,601 in the United States. None of our U.S.-based employees are represented by unions. We believe that our relations with our employees are generally good.

### Executive Officers

Our executive officers and their ages as of February 26, 2007 are as follows:

<b>Name</b>	<b>Age</b>	<b>Principal Position with Allergan</b>
David E.I. Pyott	53	Chairman of the Board and Chief Executive Officer (Principal Executive Officer)
F. Michael Ball	51	President, Allergan
James F. Barlow	48	Senior Vice President, Corporate Controller (Principal Accounting Officer)
Raymond H. Diradoorian	49	Executive Vice President, Global Technical Operations
Jeffrey L. Edwards	46	Executive Vice President, Finance and Business Development, Chief Financial Officer (Principal Financial Officer)
Douglas S. Ingram, Esq.	44	Executive Vice President, Chief Administrative Officer, General Counsel and Secretary
Scott M. Whitcup, M.D.	47	Executive Vice President, Research & Development

Officers are appointed by and hold office at the pleasure of the Board of Directors.

Mr. Pyott has been Allergan's Chief Executive Officer since January 1998 and in 2001 became the Chairman of the Board. Mr. Pyott also served as Allergan's President from January 1998 until February 2006. Previously, he was head of the Nutrition Division and a member of the executive committee of Novartis AG, a publicly-traded company focused on the research and development of products to protect and improve health and well-being, from 1995 until December 1997. From 1992 to 1995, Mr. Pyott was President and Chief Executive Officer of Sandoz Nutrition Corp., Minneapolis, Minnesota, a predecessor to Novartis, and General Manager of Sandoz Nutrition, Barcelona, Spain, from 1990 to 1992. Prior to that, Mr. Pyott held various positions within the Sandoz Nutrition group from 1980. Mr. Pyott is also a member of the board of

directors of Avery Dennison Corporation, a publicly-traded company focused on pressure-sensitive technology and self-adhesive solutions, Edwards Lifesciences Corporation, a publicly-traded company focused on products and technologies to treat advanced cardiovascular disease, Pacific Mutual Holding Company, a leading California-based life insurer, the ultimate parent company of Pacific Life and Pacific LifeCorp, the parent stockholding company of Pacific Life. Mr. Pyott is a member of the Directors Board of The Paul Merage School of Business at the University of California, Irvine (UCI) and is chair of the Chief Executive Roundtable for UCI. Mr. Pyott serves on the board of directors and the Executive Committee of the California Healthcare Institute, and the Board of the Biotechnology Industry Organization. Mr. Pyott also serves as a member of the board of directors of the Pan-American Ophthalmological Foundation, the International Council of Ophthalmology Foundation, the Cosmetic Surgery Foundation and as a member of the Advisory Board for the Foundation of the American Academy of Ophthalmology.

Mr. Ball has been President, Allergan since February 2006. Mr. Ball was Executive Vice President and President, Pharmaceuticals from October 2003 until February 2006. Prior to that, Mr. Ball was Corporate Vice President and President, North America Region and Global Eye Rx Business since May 1998 and prior to that was Corporate Vice President and President, North America Region since April 1996. He joined Allergan in 1995 as Senior Vice President, U.S. Eye Care after 12 years with Syntex Corporation, a multinational pharmaceutical company, where he held a variety of positions including President, Syntex Inc. Canada and Senior Vice President, Syntex Laboratories. Mr. Ball serves on the board of directors of SimpleTech, Inc., a publicly-traded manufacturer and marketer of computer memory and hard drive storage solutions, and Intralase Corp., a publicly-traded company that designs, develops and manufactures ultra-fast laser technology used in refractive and corneal surgery.

Mr. Barlow has been Senior Vice President, Corporate Controller since February 2005.

Mr. Barlow joined Allergan in January 2002 as Vice President, Corporate Controller. Prior to joining Allergan, Mr. Barlow served as Chief Financial Officer of Wynn Oil Company, a division of Parker Hannifin Corporation. Prior to Wynn Oil Company, Mr. Barlow was Treasurer and Controller at Wynn's International, Inc., a supplier of automotive and industrial components and specialty chemicals, from July 1990 to September 2000. Before working for Wynn's

International, Inc., Mr. Barlow was Vice President, Controller from 1986 to 1990 for Ford Equipment Leasing Company. From 1983 to 1985 Mr. Barlow worked for the accounting firm Deloitte, Haskins and Sells.

Mr. Diradoorian has served as Allergan's Executive Vice President, Global Technical Operations since February 2006. From April 2005 to February 2006, Mr. Diradoorian served as Senior Vice President, Global Technical Operations. From February 2001 to April 2005, Mr. Diradoorian served as Vice President, Global Engineering and Technology. Mr. Diradoorian joined Allergan in July 1981. Prior to joining Allergan, Mr. Diradoorian held positions at American Hospital Supply and with the Los Angeles Dodgers