ALLERGAN INC
Form 10-K
March 01, 2007

UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 10-K

(Mark One)

þ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d)**
OF THE SECURITIES EXCHANGE ACT OF 1934
For the Fiscal Year Ended December 31, 2006

or

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

Commission File No. 1-10269
Allergan, Inc.
(Exact name of Registrant as Specified in its Charter)

Delaware	**95-1622442**
(State of Incorporation)	*(I.R.S. Employer Identification No.)*
2525 Dupont Drive	**92612**
Irvine, California	*(Zip Code)*
(Address of principal executive offices)	

(714) 246-4500
(Registrant s telephone number)

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

Title of each class	**Name of each exchange on which each class registered**
Common Stock, $0.01 par value	New York Stock Exchange
Preferred Share Purchase Rights	

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 þ No o.

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 o No þ.

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 þ No o.

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. o

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

Large accelerated filer þ Accelerated filer o Non-accelerated filer o

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

As of June 30, 2006, the aggregate market value of the registrant s common stock held by non-affiliates of the registrant was approximately $16,451 million based on the closing sale price as reported on the New York Stock Exchange.

Common Stock outstanding as of February 23, 2007 153,755,944 shares (including 1,675,344 shares held in treasury).

DOCUMENTS INCORPORATED BY REFERENCE

Part III of this report incorporates certain information by reference from the registrant s proxy statement for the annual meeting of stockholders to be held on May 1, 2007, which proxy statement will be filed no later than 120 days after the close of the registrant s fiscal year ended December 31, 2006.

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Statements made by us in this report and in other reports and statements released by us that are not historical facts constitute forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21 of the Securities Exchange Act of 1934. These forward-looking statements are necessarily estimates reflecting the best judgment of our senior management based on our current estimates, expectations, forecasts and projections and include comments that express our current opinions about trends and factors that may impact future operating results. Disclosures that use words such as we believe, anticipate, estimate, intend, could, plan, expect, project of these, as well as similar expressions, are intended to identify forward-looking statements. These statements are not guarantees of future performance and rely on a number of assumptions concerning future events, many of which are outside of our control, and involve known and unknown risks and uncertainties that could cause our actual results, performance or achievements, or industry results, to differ materially from any future results, performance or achievements expressed or implied by such forward-looking statements. We discuss such risks, uncertainties and other factors throughout this report and specifically under the caption Risk Factors in Item 1A of Part I of this report below. Any such forward-looking statements, whether made in this report or elsewhere, should be considered in the context of the various disclosures made by us about our businesses including, without limitation, the risk factors discussed below. Except as required under the federal securities laws and the rules and regulations of the U.S. Securities and Exchange Commission, we do not have any intention or obligation to update publicly any forward-looking statements, whether as a result of new information, future events, changes in assumptions, or otherwise.

PART I

Item 1. *Business*

General Overview of our Business

We are a technology-driven, global health care company that discovers, develops and commercializes specialty pharmaceutical and medical device products for the ophthalmic, neurological, medical aesthetics, medical dermatological, breast aesthetics, obesity intervention and other specialty markets. We are a pioneer in specialty pharmaceutical research, targeting products and technologies related to specific disease areas such as glaucoma, retinal disease, dry eye, psoriasis, acne and movement disorders. Additionally, we discover, develop and market medical devices, aesthetics-related pharmaceuticals and over-the-counter products. Within these areas, we are an innovative leader in saline and silicone gel-filled breast implants, dermal facial fillers and obesity intervention products, therapeutic and other prescription products, and to a limited degree, over-the-counter products that are sold in more than 100 countries around the world. We are also focusing research and development efforts on new therapeutic areas, including gastroenterology, neuropathic pain and genitourinary diseases.

In June 2002, we completed the spin-off of our optical medical device business to our stockholders, forming Advanced Medical Optics, Inc., or AMO, which is now an independent, publicly-traded company. Our optical medical device business consisted of two businesses: our ophthalmic surgical products business and our contact lens care products business.

In March 2006, we completed the acquisition of Inamed Corporation, a global healthcare manufacturer and marketer of breast implants, a range of dermal products to correct facial wrinkles, and bariatric medical devices for approximately $3.3 billion, consisting of approximately $1.4 billion in cash and 17,441,693 shares of our common stock.

In January 2007, we acquired all of the outstanding capital stock of Groupe Cornéal Laboratoires, or Cornéal, a medical device manufacturer and marketer, for an aggregate purchase price of approximately $233.9 million, subject to possible post-closing adjustments based on a final determination of Cornéal s debt and cash levels. The acquisition

of Cornéal expanded our marketing rights to *Juvéderm*tm and a range of hyaluronic acid dermal fillers from the United States, Canada and Australia to all countries worldwide and provided us with control over the manufacturing process and future development of *Juvéderm*tm.

Our Internet website address is *www.allergan.com*. We make our periodic and current reports, together with amendments to these reports, available on our Internet website, free of charge, as soon as reasonably practicable after such material is electronically filed with, or furnished to, the Securities and Exchange Commission. The information on our Internet website is not incorporated by reference into this Annual Report on Form 10-K.

Operating Segments

Following our spin-off of AMO and through the first fiscal quarter of 2006, we operated our business on the basis of a single reportable segment specialty pharmaceuticals. Due to the Inamed acquisition, beginning in the second fiscal quarter of 2006, we operated our business on the basis of two reportable segments specialty pharmaceuticals and medical devices. The specialty pharmaceuticals segment produces a broad range of pharmaceutical products, including: ophthalmic products for glaucoma therapy, ocular inflammation, infection, allergy and dry eye; skin care products for acne, psoriasis and other prescription and over-the-counter dermatological products; and *Botox*® for certain therapeutic and aesthetic indications. The medical devices segment produces breast implants for aesthetic augmentation and reconstructive surgery; facial aesthetics products; and the *LAP-BAND*® Intragastric Banding System, or *LAP-BAND*® System, designed to treat severe and morbid obesity and the *BIB*™ *BioEnterics*® Intragastric Balloon, or *BIB*™ System, for the treatment of obesity. We provide global marketing strategy teams to coordinate the development and execution of a consistent marketing strategy for our products in all geographic regions that share similar distribution channels and customers. The following table sets forth, for the periods indicated, product net sales for each of our product lines within our specialty pharmaceuticals segment, product net sales for each of our product lines within our medical devices segment, domestic and international sales as a percentage of total product net sales within our specialty pharmaceuticals segment and medical devices segment, and segment operating income for our specialty pharmaceuticals segment and medical devices segment:

	Year Ended December 31,		
	2006	2005	2004
		(in millions)	
Specialty Pharmaceuticals Segment Product Net Sales by Product Line			
Eye Care Pharmaceuticals	$ 1,530.6	$ 1,321.7	$ 1,137.1
Botox®/Neuromodulator	982.2	830.9	705.1
Skin Care Products	125.7	120.2	103.4
Other(1)		46.4	100.0
Total Specialty Pharmaceuticals Segment Product Net Sales	$ 2,638.5	$ 2,319.2	$ 2,045.6
Specialty Pharmaceuticals Segment Product Net Sales			
Domestic	67.9%	67.5%	69.1%
International	32.1%	32.5%	30.9%
Medical Devices Segment Product Net Sales by Product Line(3)			
Breast Aesthetics	$ 177.2	$	$
Obesity Intervention	142.3		
Facial Aesthetics	52.1		
Total Medical Devices Segment Product Net Sales	$ 371.6	$	$
Medical Devices Segment Product Net Sales(3)			
Domestic	64.2%	%	%

International	35.8%	%	%
Specialty Pharmaceuticals Segment Operating Income(2)	$ 888.8	$ 762.9	$ 684.7
Medical Devices Segment Operating Income(2)(3)	119.9		
Consolidated Long-Lived Assets			
Domestic	$ 3,279.0	$ 470.7	$ 360.7
International	244.0	199.3	197.2

(1) Other sales primarily consist of sales to AMO pursuant to a manufacturing and supply agreement entered into as part of the AMO spin-off that terminated as scheduled in June 2005.

(2) Management evaluates business segment performance on an operating income basis exclusive of general and administrative expenses and other indirect costs, restructuring charges, in-process research and development expenses, amortization of identifiable intangible assets related to the Inamed acquisition and certain other adjustments, which are not allocated to our business segments for performance assessment by our chief operating decision maker. Other adjustments excluded from our business segments for purposes of performance assessment represent income or expenses that do not reflect, according to established company-defined criteria, operating income or expenses associated with our core business activities.

(3) Due to the Inamed acquisition, beginning in the second quarter of 2006, we operated our business on the basis of two reportable segments specialty pharmaceuticals and medical devices.

We do not discretely allocate assets to our operating segments, nor does our chief operating decision maker evaluate operating segments using discrete asset information.

See Note 14, Business Segment Information, in the notes to the consolidated financial statements listed under Item 15 of Part IV of this report, Exhibits and Financial Statement Schedules, for further information concerning our foreign and domestic operations.

Specialty Pharmaceuticals Segment

Eye Care Pharmaceuticals Product Line

We develop, manufacture and market a broad range of prescription and non-prescription products designed to treat diseases and disorders of the eye, including glaucoma, dry eye, inflammation, infection and allergy.

Glaucoma. The largest segment of the market for ophthalmic prescription drugs is for the treatment of glaucoma, a sight-threatening disease typically characterized by elevated intraocular pressure leading to optic nerve damage. Glaucoma is currently the world s second leading cause of blindness, and we estimate that over 60 million people worldwide have glaucoma. According to IMS Health Inc., an independent marketing research firm, our products for the treatment of glaucoma, including *Alphagan*® (brimonide tartrate ophthalmic solution) 0.2%, or *Alphagan*®, *Alphagan*® *P* (brimonide tartrate ophthalmic solution) 0.15%, or *Alphagan*® *P, Alphagan*® *P* 0.1% (brimonide tartrate ophthalmic solution) 0.1%, or *Alphagan*® *P* 0.1%, and *Lumigan*® (bimatoprost ophthalmic solution) 0.03%, captured approximately 17% of the worldwide glaucoma market for the first nine months of 2006. *Lumigan*® is now our largest selling eye care product. According to IMS Health, Inc., *Lumigan*® was the third largest selling glaucoma product in the world for the first nine months of 2006.

Our second largest selling eye care pharmaceutical products are the ophthalmic solutions *Alphagan*®, *Alphagan*® *P*, and *Alphagan*® *P* 0.1%. *Alphagan*®, *Alphagan*® *P* and *Alphagan*® *P* 0.1% lower intraocular pressure by reducing aqueous humor production and increasing uveoscleral outflow. *Alphagan*® *P* and *Alphagan*® *P* 0.1% are improved reformulations of *Alphagan*® containing brimonidine, *Alphagan*® s active ingredient, preserved with *Purite*®. We currently market *Alphagan*®, *Alphagan*® *P,* and *Alphagan*® *P* 0.1% in over 70 countries worldwide.

Alphagan®, *Alphagan*® *P*, and *Alphagan*® *P* 0.1% combined were the fifth best selling glaucoma products in the world for the first nine months of 2006, according to IMS Health Inc. Combined sales of *Alphagan*®, *Alphagan*® *P* and *Alphagan*® *P* 0.1%, and our glaucoma and ocular hypertension product *Combigan*tm (brimonidine tartrate 0.2%/timolol maleate ophthalmic solution 0.5%), discussed below, represented approximately 10% of our total consolidated product net sales in 2006, 12% of our total consolidated product net sales in 2005 and 13% of our total consolidated product net sales in 2004. The decline in the percentage of our total net sales represented by sales of

Alphagan®, *Alphagan*® *P*, *Alphagan*® *P* 0.1% and *Combigan*™ primarily resulted from the significant increase in our net sales in 2006 as a result of the Inamed acquisition. In July 2002, based on the acceptance of *Alphagan*® *P*, we discontinued the U.S. distribution of *Alphagan*®. In May 2004, we entered into an exclusive licensing agreement with Kyorin Pharmaceutical Co., Ltd., under which Kyorin became responsible for the development and commercialization of *Alphagan*® and *Alphagan*® *P* in Japan s ophthalmic specialty area. 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 agreed to work collaboratively with Senju on overall product strategy

and management. *Alphagan® P* 0.1% was launched in the U.S. market in the first quarter of 2006. The marketing exclusivity period for *Alphagan® P* expired in the United States in September 2004 and the marketing exclusivity period for *Alphagan® P* 0.1% will expire in August 2008, although we have a number of patents covering the *Alphagan® P* and *Alphagan® P* 0.1% technology that extend to 2021 in the United States and 2009 in Europe, with corresponding patents pending in Europe. In May 2003, the FDA approved the first generic form of *Alphagan®*. Additionally, a generic form of *Alphagan®* is sold in a limited number of other countries, including Canada, Mexico, India, Brazil, Colombia and Argentina. 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 further information regarding litigation involving *Alphagan®*. 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® 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® P* have been converted to other brimonidine-containing products we market has increased to a specified threshold.

Lumigan® is a topical treatment indicated for the reduction of elevated intraocular pressure in patients with glaucoma or ocular hypertension who are either intolerant or insufficiently responsive when treated with other intraocular pressure-lowering medications. We currently sell *Lumigan®* in over 50 countries worldwide. Sales of *Lumigan®* represented approximately 11% of our total consolidated product net sales in 2006, 12% of our total consolidated product net sales in 2005 and 11% of our total consolidated product net sales in 2004. The decline in the percentage of our total net sales in 2006 compared to 2005 represented by sales of *Lumigan®* primarily resulted from the significant increase in our net sales in 2006 as a result of the Inamed acquisition. In March 2002, the European Commission approved *Lumigan®* through its centralized procedure. In January 2004, the European Union s Committee for Proprietary Medicinal Products approved *Lumigan®* as a first-line therapy for the reduction of elevated intraocular pressure in chronic open-angle glaucoma and ocular hypertension. In June 2006, the FDA approved *Lumigan®* as a first-line therapy. In May 2004, we entered into an exclusive licensing agreement with Senju Pharmaceutical Co., Ltd., under which Senju became responsible for the development and commercialization of *Lumigan®* in Japan. Senju incurs associated costs, makes clinical development and commercialization milestone payments and makes royalty-based payments on product sales. We agreed to work collaboratively with Senju on overall product strategy and management. In November 2003, we filed a New Drug Application with the FDA for a *Lumigan®* and timolol combination designed to treat glaucoma or ocular hypertension. In August 2004, we announced that the FDA issued an approvable letter regarding *Ganfort®*, the *Lumigan®* and timolol combination, setting out the conditions, including additional clinical investigation, that we must meet in order to obtain final FDA approval. In May 2006, we received a license from the European Commission to market *Ganfort®* in the European Union.

In addition to our *Alphagan®* and *Lumigan®* products, we have developed the ophthalmic solution *Combigan™*, a brimonidine and timolol combination designed to treat glaucoma and ocular hypertension (high pressure in the eye) in people who are not responsive to treatment with only one medication and are considered appropriate candidates for combination therapy. Outside the United States, *Combigan™* is now approved and has been launched in over 30 countries worldwide, including Canada, Australia, New Zealand, across Latin America and Asia, as well as Europe. In September 2005, we received a positive opinion from the European Union by way of the Mutual Recognition Process for *Combigan™* in all twenty-one concerned member states in which we filed. In March 2005, the FDA issued an approvable letter for our brimonidine and timolol combination and in December 2006, the FDA issued an approvable letter for *Combigan™*. The approvable letter outlines the remaining conditions that we must meet in order to obtain FDA final marketing approval.

Ocular Surface Disease. Restasis® (cyclosporine ophthalmic emulsion) 0.05% is the first and currently the only prescription therapy for the treatment of chronic dry eye disease. Dry eye disease is a painful and irritating condition

involving abnormalities and deficiencies in the tear film initiated by a variety of causes. The incidence of dry eye disease increases markedly with age, after menopause in women and in people with systemic diseases such as Sjogren s syndrome and rheumatoid arthritis. Until the approval of *Restasis*®, physicians used lubricating tears as a temporary measure to provide palliative relief of the debilitating symptoms of dry eye disease. We launched

Restasis® in the United States in April 2003 under a license from Novartis for the ophthalmic use of cyclosporine. *Restasis*® is currently approved in 26 countries. In April 2005, we entered into a royalty buy-out agreement with Novartis related to *Restasis*® and agreed to pay $110 million to Novartis in exchange for Novartis worldwide rights and obligations, excluding Japan, for technology, patents and products relating to the topical ophthalmic use of cyclosporine A, the active ingredient in *Restasis*®. Under the royalty buy-out agreement, we no longer make royalty payments to Novartis in connection with our sales of *Restasis*®.

In June 2001, we entered into a licensing, development and marketing agreement with Inspire Pharmaceuticals, Inc. under which we obtained an exclusive license to develop and commercialize Inspire s INS365 Ophthalmic, a treatment to relieve the signs of dry eye disease by rehydrating conjunctival mucosa and increasing non-lacrimal tear component production, in exchange for our agreement to make royalty payments to Inspire on sales of both *Restasis*® and, ultimately, INS365, and for Inspire to promote *Restasis*® in the United States. In December 2003, the FDA issued an approvable letter for INS365 and also requested additional clinical data. In February 2005, Inspire announced that INS365 failed to demonstrate statistically significant improvement as compared to a placebo for the primary endpoint of the incidence of corneal clearing. Inspire also announced that INS365 achieved improvement compared to a placebo for a number of secondary endpoints. Inspire filed a New Drug Application amendment with the FDA in the second quarter of 2005. In December 2005, Inspire announced that it had received a second approvable letter from the FDA in connection with INS365.

Ophthalmic Inflammation. Our leading ophthalmic anti-inflammatory product is *Acular*® (ketorolac ophthalmic solution) 0.5%. *Acular*® is a registered trademark of and is licensed from its developer, Syntex (U.S.A.) Inc., a business unit of Hoffmann-LaRoche Inc. *Acular*® is indicated for the temporary relief of itch associated with seasonal allergic conjunctivitis, the inflammation of the mucus membrane that lines the inner surface of the eyelids, and for the treatment of post-operative inflammation in patients who have undergone cataract extraction. *Acular PF*® was the first, and currently remains the only, unit-dose, preservative-free topical non-steroidal anti-inflammatory drug, or NSAID, in the United States. *Acular PF*® is indicated for the reduction of ocular pain and photophobia following incisional refractive surgery. The *Acular*® franchise was the highest selling ophthalmic NSAID in the world during the first nine months of 2006, according to IMS Health, Inc. Our *Acular LS*® (ketorolac ophthalmic solution) 0.4% product is a version of *Acular*® that has been reformulated for the reduction of ocular pain, burning and stinging following corneal refractive surgery.

Our product *Pred Forte*® remains a leading topical steroid worldwide based on 2006 sales. *Pred Forte*® has no patent protection or marketing exclusivity and faces generic competition.

Ophthalmic Infection. Our *Ocuflox*®*/Oflox*®*/Exocin*® ophthalmic solution is a leading product in the ophthalmic anti-infective market. *Ocuflox*® has no patent protection or marketing exclusivity and faces generic competition.

We license *Zymar*® (gatifloxacin ophthalmic solution) 0.3% from Kyorin Pharmaceutical Co. Ltd., and have worldwide ophthalmic rights excluding Japan, Korea, Taiwan and certain other countries in Asia. We launched *Zymar*® in the United States in April 2003. *Zymar*® is a fourth-generation fluoroquinolone for the treatment of bacterial conjunctivitis and is currently approved in 21 countries. Laboratory studies have shown that *Zymar*® kills the most common bacteria that cause eye infections as well as specific resistant bacteria. According to Verispan, an independent research firm, *Zymar*® was the number one ophthalmic anti-infective prescribed by ophthalmologists in the United States in 2006. *Zymar*® was the third best selling ophthalmic anti-infective product in the world (and second in the United States) for the first nine months of 2006, according to IMS Health, Inc.

Allergy. The allergy market is, by its nature, a seasonal market, peaking during the spring months. We market *Alocril*® ophthalmic solution for the treatment of itch associated with allergic conjunctivitis. We license *Alocril*® from Fisons Ltd., now a business unit of Sanofi-Aventis, and hold worldwide ophthalmic rights excluding Japan. *Alocril*® is

approved in the United States, Canada and Mexico. We license *Elestat*® from Boehringer Ingelheim AG, and hold worldwide ophthalmic rights excluding Japan. We co-promote *Elestat*® (epinastine ophthalmic solution) 0.05% in the United States under an agreement with Inspire within the ophthalmic specialty area and to allergists. *Elestat*® is used for the prevention of itching associated with allergic conjunctivitis. Under the terms of our agreement with Inspire, Inspire provided us with an up-front payment and we make payments to Inspire based on *Elestat*® net sales. In addition, the agreement reduced our existing royalty payment to Inspire for *Restasis*®. Inspire

has primary responsibility for selling and marketing activities in the United States related to *Elestat*®. We have retained all international marketing and selling rights. We launched *Elestat*® in Europe under the brand names *Relestat*® and *Purivist*® during 2004, and Inspire launched *Elestat*® in the United States during 2004. *Elestat*®/*Relestat*®/*Purivist*® is currently approved in 38 countries and was the third best selling ophthalmic allergy product in the world (and second in the United States) for the first nine months of 2006, according to IMS Health, Inc.

Neuromodulator

Our neuromodulator product, *Botox*® (Botulinum Toxin Type A), is used for a wide variety of treatments that continue to expand. *Botox*® is accepted in many global regions as the standard therapy for indications ranging from therapeutic neuromuscular disorders and related pain to cosmetic facial aesthetics. There are currently in excess of 100 therapeutic and aesthetic uses for *Botox*® reported in the medical literature. The versatility of *Botox*® is based on its localized treatment effect and approximately 18 years of safety experience in large patient groups. Marketed as *Botox*®, *Botox*® Cosmetic*, Vistabel*® or *Vistabex*®, depending on the indication and country of approval, the product is currently approved in approximately 75 countries for up to 20 unique indications. Sales of *Botox*® represented approximately 33%, 36% and 34% of our total consolidated product net sales in 2006, 2005 and 2004, respectively.

Botox®. *Botox*® is used therapeutically for the treatment of certain neuromuscular disorders which are characterized by involuntary muscle contractions or spasms. The approved therapeutic indications for *Botox*® in the United States are as follows:

blepharospasm, the uncontrollable contraction of the eyelid muscles which can force the eye closed and result in functional blindness;

strabismus, or misalignment of the eyes, in people 12 years of age and over;

cervical dystonia, or sustained contractions or spasms of muscles in the shoulders or neck in adults, along with associated pain; and

severe primary axillary hyperhidrosis (underarm sweating) that is inadequately managed with topical agents.

In many countries outside of the United States, *Botox*® is also approved for treating hemifacial spasm, pediatric cerebral palsy, and post-stroke focal spasticity. We are currently pursuing approvals for *Botox*® in the United States and Europe for new indications, including headache, post-stroke focal spasticity, overactive bladder and benign prostatic hypertrophy. In April 2005, we announced plans to move forward with a large Phase III clinical trial program to investigate the safety and efficacy of *Botox*® as a prophylactic therapy in a subset of migraine patients with chronic daily headache, and in May 2005, we reached agreement with the FDA to enter Phase III clinical trials for *Botox*® to treat neurogenic overactive bladder and Phase II clinical trials for *Botox*® to treat idiopathic overactive bladder. In December 2005, we initiated Phase II clinical trials for *Botox*® to treat benign prostatic hypertrophy.

Botox® *Cosmetic.* The FDA has approved *Botox*® for the temporary improvement in the appearance of moderate to severe glabellar lines in adult men and women age 65 or younger. Referred to as *Botox*®*, Botox*® Cosmetic*, Vistabel*® or *Vistabex*®, depending on the country of approval, this product is designed to relax wrinkle-causing muscles to smooth the deep, persistent, glabellar lines between the brow that often develop during the aging process. Currently, over 50 countries have approved the glabellar line indication for *Botox*®, *Botox*® Cosmetic, *Vistabel*® or *Vistabex*®. Health Canada, the Canadian national regulatory body, also approved *Botox*® Cosmetic for the treatment of upper facial lines in November 2005. In 2005, we extended our previously launched direct-to-consumer marketing campaigns in Canada and the United States. These campaigns included television commercials and print advertising aimed at consumers and aesthetic specialty physicians. We continue to sponsor training of aesthetic specialty

physicians in approved countries to further expand the base of qualified physicians using *Botox®, Botox®* Cosmetic, *Vistabel®* or *Vistabex®*. With the integration of the former Inamed medical products into our TOTAL FACIAL REJUVENATION™ portfolio, we now have a worldwide leadership position in the facial aesthetic market.

In October 2005, we entered into a long-term arrangement with GlaxoSmithKline (GSK) under which GSK agreed to develop and promote *Botox®* in Japan and China and we agreed to co-promote GSK s products *ImitrexSTATdose System®* (sumatriptan succinate) and *Amerge®* (naratriptan hydrochloride) in the United

States. Under the terms of the arrangement, we licensed to GSK all clinical development and commercial rights to *Botox*® in Japan and China, markets in which GSK has extensive commercial, regulatory and research and development resources, as well as expertise in neurology. We received an up-front payment and receive payments for research and development and marketing support, and royalties on GSK s Japan and China *Botox*® sales. We also manufacture *Botox*® for GSK as part of a long-term supply agreement and collaboratively support GSK on new clinical developments for *Botox*® and strategic marketing in those markets. In addition, we obtained the right to co-promote GSK s products *ImitrexSTATdose System*® and *Amerge*® in the United States to neurologists for a 5-year period. *ImitrexSTATdose System*® is approved for the treatment of acute migraine in adults and for the acute treatment of cluster headache episodes. *Amerge*® tablets are approved for the acute treatment of migraine attacks with and without an aura in adults. Our agreement with GSK provides that we receive fixed and performance payments from GSK in connection with our co-promotion of *ImitrexSTATdose System*® and *Amerge*®.

Skin Care Product Line

Our skin care product line focuses on the psoriasis and acne markets, particularly in the United States and Canada.

Tazarotene Products. We market *Tazorac*® gel in the United States for the treatment of plaque psoriasis, a chronic skin disease characterized by dry red patches, and acne. We also market a cream formulation of *Tazorac*® in the United States for the treatment of psoriasis and the topical treatment of acne. We have also engaged Pierre Fabre Dermatologie as our promotion partner for *Zorac*® in certain parts of Europe, the Middle East and Africa.

Our product *Avage*® is a tazarotene cream indicated for the treatment of facial fine wrinkling, mottled hypo- and hyperpigmentation (blotchy skin discoloration) and benign facial lentigines (flat patches of skin discoloration) in patients using a comprehensive skin care and sunlight avoidance program. We launched *Avage*® in the United States in January 2003.

In January 2005, we launched *Prevage*™ cream, containing 1% idebenone, a clinically tested antioxidant designed to reduce the appearance of fine lines and wrinkles, as well as provide protection against environmental factors, including sun damage, air pollution and cigarette smoke. In May 2005, we entered into an exclusive co-marketing agreement with Elizabeth Arden, Inc. to globally market a new formulation of *Prevage*™ containing 0.5% idebenone, to leading department stores and other prestige cosmetic retailers. In September 2005, we began marketing *Prevage*™ MD, containing 1% idebenone, to physicians.

Azelex®. *Azelex*® cream is approved by the FDA for the topical treatment of mild to moderate inflammatory acne vulgaris and is licensed from Intendis GmbH, a division of Bayer Schering Pharma AG. We market *Azelex*® cream primarily in the United States.

M.D. Forte®. We develop and market glycolic acid-based skin care products. We market our *M.D. Forte*® line of alpha hydroxy acid products to physicians.

Finacea®. Through a collaboration with Intendis GmbH, we jointly promote Intendis topical rosacea treatment, *Finacea*® (azelaic acid gel 15%). *Finacea*® is approved by the FDA for the treatment of rosacea and holds a leading position in the market.

Medical Devices Segment

Breast Aesthetics

We develop, manufacture, and market a diverse line of breast implants, consisting of a variety of shapes, sizes, and textures. Our breast implants consist of a silicone elastomer shell filled with either a saline solution or silicone gel with varying degrees of cohesivity. This shell can consist of either a smooth or textured surface. We market our breast implants under the trade names *McGhan*® and *CUI*® and the trademarks *BioCell*®, *MicroCell*®, *BioDimensional*™, and *Inamed*®. Our breast implants are available in a large number of variations to meet customers preferences and needs.

Saline-Filled Breast Implants. We sell saline-filled breast implants in the United States and internationally for use in breast augmentation for cosmetic or revision reasons and for reconstructive surgery. The U.S. market is the primary consumer of our saline-filled breast implants.

Silicone Gel-Filled Breast Implants. We sell silicone gel-filled breast implants primarily in Europe, the Middle East, Latin America, Australia, New Zealand and Asia. More than 90% of our breast implant sales outside the United States and Canada are silicone gel-filled. There are a variety of silicone gel-filled breast implants available in these markets based upon the degrees of cohesivity of the silicone gel-filler material. In October 2006, Health Canada granted us a medical device license with conditions to sell and market silicone gel-filled breast implants, including our round, smooth and textured silicone gel-filled breast implants and Style 410 shaped and textured implants, for use in breast augmentation, reconstruction and revision surgery. In November 2006, the FDA approved our round silicone gel-filled breast implants for breast augmentation. FDA approval was conditioned on our continuation of our core clinical study and our pre-clinical studies, our completion of a focus group study regarding format and content of patient labeling, our distribution of labeling to physicians and patients within sufficient time prior to surgery to fully consider the risks associated with breast implant surgery, our termination of new enrollment into an adjunct study and continuation of follow-up for currently enrolled patients and our initiation of a 10-year prospective study, of 40,000 patients with silicone gel-filled implants and 20,000 patients with saline-filled implants, to further validate the long-term safety and effectiveness of silicone gel-filled breast implants.

Tissue Expanders. We sell a line of tissue expanders for breast reconstruction and as an alternative to skin grafting to cover burn scars and correct birth defects.

Facial Aesthetics

We develop, manufacture, and market dermal filler products designed to improve facial appearance by smoothing wrinkles and scars and enhancing the definition of facial structure. Our primary facial aesthetics products are *Zyderm*® and *Zyplast*®, *CosmoDerm*® and *CosmoPlast*®, the *Juvéderm*™/*Hydrafill*™/*Surgiderm*® product range, the *Hylaform*® product range and *Captique*™.

Zyderm® and *Zyplast*®. *Zyderm*® and *Zyplast*® dermal fillers are injectable formulations of bovine collagen. *Zyderm*® implants are formulated for people with fine line wrinkles or superficial facial contour defects. These implants are particularly effective in smoothing delicate frown and smile lines, and fine creases that develop at the corners of the eyes and above and below the lips, and can also help correct certain shallow scars. *Zyplast*® implants are designed to treat deeper depressions and can be used for more pronounced contour problems, such as deeper scars, lines and furrows, and for areas upon which more force is exerted, such as the corners of the mouth. The implants take on the texture and appearance of human tissue and are subject to similar stresses and aging processes. Consequently, supplemental treatments are necessary to maintain the desired result. *Zyderm*® and *Zyplast*® implants require a skin test, with a requisite 30-day period to observe the possibility of allergic reaction in the recipient. Both of these products are formulated with Lidocaine, an anesthetic, to alleviate pain during injection. *Zyderm*® and *Zyplast*® are approved for marketing in the United States and Europe.

CosmoDerm® and CosmoPlast®. *CosmoDerm*® and *CosmoPlast*® dermal fillers are a line of injectable human skin-cell derived collagen products that we license from Smith & Nephew, Inc. *CosmoDerm*® implants are formulated for people with fine line wrinkles or superficial facial contour defects. These implants are particularly effective in smoothing delicate frown and smile lines and fine creases that develop at the corners of the eyes and above and below the lips and can also help correct certain shallow scars. *CosmoPlast*® implants are designed to treat deeper depressions and can be used for more pronounced contour problems, such as deeper scars, lines and furrows, and for areas upon which more force is exerted, such as the corners of the mouth. The implants take on the texture and appearance of

human tissue and are subject to similar stresses and aging processes. Consequently, supplemental treatments are necessary to maintain the desired result. *CosmoDerm*® and *CosmoPlast*® implants do not require a skin test pre-treatment. Both of these products are formulated with Lidocaine, an anesthetic, to alleviate pain during injection. We received FDA approval for *CosmoDerm*® and *CosmoPlast*® in March 2003 and received approval from Health Canada in December 2002. We received approval to market *CosmoDerm*® and *CosmoPlast*® in a number of European countries in 2004.

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.

Hylaform® Gel. *Hylaform®* 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 *Hylaform®* from Genzyme Corporation. *Hylaform®* does not require a skin test, so patients can be treated immediately. In 2001, two new formulations of *Hylaform®* gel were developed: *Hylaform®* FineLine, designed especially for people with fine line wrinkles or superficial facial contour defects, and *Hylaform®* Plus, formulated for treating deeper depressions and more pronounced contour problems such as deeper scars, lines, and furrows. We launched *Hylaform®* FineLine and *Hylaform®* 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®* gel. In January 2002, the HCTPP approved both *Hylaform®* Plus and *Hylaform®* 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®* Plus in the United States.

Juvéderm™/Hydrafill™. Our product *Juvéderm™* 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™* 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™* is marketed under the trademark *Hydrafill™*. *Juvéderm™* and *Hydrafill™* 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™*, *Surgiderm®*, *Voluma®* and other hyaluronic acid dermal fillers to all countries worldwide and obtained control over the manufacturing process and future development of *Juvéderm™* and the company s R&D pipeline. *Juvéderm™* products are currently approved or registered in over 34 countries, including all major European markets. In these markets, *Juvéderm™* does not require a skin test pre-treatment. Distribution of *Juvéderm™* in Canada and key European markets commenced in 2004. In June 2006, the FDA approved the *Juvéderm™* dermal filler family of products and in September 2006, we launched the next-generation hyaluronic acid-based dermal filler products, *Juvéderm™* Ultra and *Juvéderm™* 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™. *Captique™* 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™* from Genzyme Corporation. *Captique™* 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*® 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*® 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*® System procedure is adjustable and reversible.

The *LAP-BAND*® 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*® 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*®, which was approved by the FDA in January 2004. The *LAP-BAND VG*® 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*® serves those who are physically larger, have thicker gastric walls, or have substantial internal fat. Over 300,000 *LAP-BAND*® System units have been sold worldwide since 1993.

We also sell the *BIB*™ 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*™ 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*™ 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® 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*®. 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*® Cosmetic, *Botox*® for hyperhidrosis, *Restasis*®, *Refresh*® artificial tears and the *LAP-BAND*® 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*®, 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*® for the ophthalmic specialty market in Japan. Under the terms of the agreement, Sanwa is responsible for the development and commercialization of *Posurdex*® in Japan and associated costs. Sanwa pays us a royalty based on net sales of *Posurdex*® 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*®, 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*®. We are focused on both expanding the approved indications for *Botox*® and pursuing new neuromodulator-based therapeutics. This includes expanding the approved uses for *Botox*® to include treatment for spasticity, headache, brow furrow and urologic conditions, including overactive bladder. Also, we are conducting Phase II clinical trials of *Botox*® 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*® for the treatment of palmar hyperhydrosis, as part of our conditions of approval for axiliar hyperhidrosis by the FDA .

In connection with our obesity intervention products, we are planning to conduct clinical trials of the *BIB*™ 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*™ 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*®. 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® 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® 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®*. Pursuant to a federal court ruling in June 2006, Apotex is barred from obtaining approval before our *Acular®* 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®* was the only neuromodulator approved by the FDA. At that time, the FDA approved *Myobloc®*, a neuromodulator formerly marketed by Elan Pharmaceuticals and now marketed by Solstice Neurosciences Inc. Beaufour Ipsen Ltd. is seeking FDA approval of its *Dysport®* neuromodulator for certain therapeutic indications, and Medicis Pharmaceutical Corporation, its licensee for the United States, Canada and Japan, is seeking approval of *Reloxin®* for cosmetic indications. Beaufour Ipsen has marketed *Dysport®* in Europe since 1991, prior to our European commercialization of *Botox®* in 1992. In June 2006, Beaufour Ipsen received the marketing authorization for a cosmetic indication for *Dysport®* in Germany. In 2007, Beaufour Ipsen granted an exclusive development and marketing license for *Dysport®* to Galderma, a joint venture between Nestle and L Oreal, 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®* 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®* 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®*, 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®*, 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 Prostheses, 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®, Restylane®* Fine Lines, and *Perlane*™ (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®*, which is distributed by Medicis. Also, in 2006, *Radiesse®*, a filler from BioForm Medical, Inc., received approval in the United States.

Obesity Intervention. No gastric bands other than our *LAP-BAND®* 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®* System upon entry to the U.S. market. Outside the United States, the *LAP-BAND®* 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®* 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 FFDCA, 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 FFDCA, 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 FFDCA. 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 FFDCA 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*® and *Alphagan*® *P,* and the U.S. patents relating to *Restasis*®, *Acular*® and *Zymar*®, 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*® currently expire in 2015. The European patent covering *Lumigan*® expires in various countries between 2013 and 2017. The U.S. patent covering the commercial formulation of *Acular*® expires in 2009 and in 2008 in Europe. The U.S. patents covering the commercial formulation of *Alphagan*® *P* expire in 2012 and 2021 and in 2009 in Europe, with corresponding patents pending. The U.S. patents covering *Restasis*® expire in 2009 and 2014. *Zymar*® 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*® and *Alphagan*® *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*® 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*®. In April 2005, we entered into a royalty buy-out agreement with Novartis related to *Restasis*® 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*® products since 1999, including *Hylaform*® Plus and *Hylaform*® 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*™, 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*® product. Specifically, sales of *Botox*® 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*® 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*® 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*® System product. For instance, the Technology Evaluation Center of the Blue Cross/Blue Shield National Association provided a positive assessment of the *LAP-BAND*® 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*™ 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:

Name	Age	Principal Position with Allergan
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 baseball team.

Mr. Edwards has been Executive Vice President, Finance and Business Development, Chief Financial Officer since September 2005. Prior to that, Mr. Edwards was Corporate Vice President, Corporate Development since March 2003 and previously served as Senior Vice President Treasury, Tax, and Investor Relations. He joined Allergan in 1993. Prior to joining Allergan, Mr. Edwards was with Banque Paribas and Security Pacific National Bank, where he held various senior level positions in the credit and business development functions.

Mr. Ingram has been Executive Vice President, Chief Administrative Officer, General Counsel and Secretary, as well as our Chief Ethics Officer, since October 2006. From October 2003 through October 2006, Mr. Ingram served as Executive Vice President, General Counsel and Secretary, as well as our Chief Ethics Officer. Mr. Ingram currently manages the Global Legal Affairs organization, Global Regulatory Affairs, Compliance and Internal Audit, Corporate Communications, Global Trade Compliance, the Global Human Resources organization and the Information Technology organization. Prior to that, Mr. Ingram served as Corporate Vice President, General Counsel and Secretary, as well as our Chief Ethics Officer, since July 2001. Prior thereto he was Senior Vice President and General Counsel since January 2001, and Assistant Secretary since November 1998. Prior to that, Mr. Ingram was Associate General Counsel from August 1998, Assistant General Counsel from January 1998 and Senior Attorney and Chief Litigation Counsel from March 1996, when he first joined Allergan. Prior to joining Allergan, Mr. Ingram was, from August 1988 to March 1996, an attorney with the law firm of Gibson, Dunn & Crutcher. Mr. Ingram serves as a member of the board of directors of Volcom, Inc., a publicly-traded designer and distributor of clothing and accessories.

Dr. Whitcup has been Executive Vice President, Research and Development since July 2004. Dr. Whitcup joined Allergan in January 2000 as Vice President, Development, Ophthalmology. In January 2004, Dr. Whitcup became Allergan s Senior Vice President, Development, Ophthalmology. From 1993 until 2000, Dr. Whitcup served as the Clinical Director of the National Eye Institute at the National Institutes of Health. As Clinical Director, Dr. Whitcup s leadership was vital in building the clinical research program and promoting new ophthalmic therapeutic discoveries. Dr. Whitcup is a faculty member at the Jules Stein Eye Institute/David Geffen School of Medicine at the University of California, Los Angeles. Dr. Whitcup serves on the board of directors of Avanir Pharmaceuticals, a publicly-traded pharmaceutical company.

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

We operate in a rapidly changing environment that involves a number of risks. The following discussion highlights some of these risks and others are discussed elsewhere in this report. These and other risks could materially and adversely affect our business, financial condition, prospects, operating results or cash flows. The following risk factors are not an exhaustive list of the risks associated with our business. New factors may emerge or changes to these risks could occur that could materially affect our business.

We operate in a highly competitive business.

The pharmaceutical and medical device industries are highly competitive and they 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.

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.

It is possible that developments by our competitors could make our products or technologies less competitive or obsolete. Our future growth depends, in part, on our ability to develop products which are more effective. For instance, 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. Sales of our existing products may decline rapidly if a new product is introduced by one of our competitors or if we announce a new product that, in either case, represents a substantial improvement over our existing products. Similarly, if we fail to make sufficient investments in research and development programs, our current and planned products could be surpassed by more effective or advanced products developed by our competitors.

Until December 2000, *Botox*® was the only neuromodulator approved by the FDA. At that time, the FDA approved *Myobloc*®, a neuromodulator formerly marketed by Elan Pharmaceuticals and now marketed by Solstice Neurosciences, Inc. Beaufour Ipsen Ltd. is seeking FDA approval of its *Dysport*® neuromodulator for certain therapeutic indications, and Medicis, its licensee for the United States, Canada and Japan, is seeking approval of *Reloxin*® for cosmetic indications. Beaufour Ipsen has marketed *Dysport*® in Europe since 1991, prior to our European commercialization of *Botox*® in 1992. In June 2006, Beaufour Ipsen received the marketing authorization for a cosmetic indication for *Dysport*® in Germany. In 2007, Beaufour Ipsen granted an exclusive development and marketing license for *Dysport*® to Galderma 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. *Reloxin*® is also currently under review for use in aesthetic medicine indications by the French regulatory authorities as part of an application for a license across the European Union.

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, or cGMP, regulations, 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 from German authorities for *Xeomin*® and launched its product in July 2005, and a Korean botulinum toxin, *Neuronox*®, 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*®, with the exception of certain countries in Asia where Medy-Tox may retain the marketing rights. Our sales of *Botox*® could be materially and negatively impacted by this competition or competition from other companies that might obtain FDA approval or approval from other regulatory authorities to market a neuromodulator.

Mentor Corporation is our principal competitor in the United States for breast implants. 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 Prostheses, Nagor, Laboratories Sebbin, and LPI.

Medicis Pharmaceutical Corporation began marketing *Restylane*®, a dermal filler, in January 2004. Through our purchase of Inamed, we acquired the rights to sell a competing dermal filler, *Juvéderm*™, in the United States, Canada and Australia and *Hydrafill*™ in certain European countries. *Juvéderm*™ was approved by the FDA for sale in the United States in June 2006, and we announced nationwide availability of *Juvéderm*™ in January 2007. We cannot assure you that *Juvéderm*™ will offer equivalent or greater facial aesthetic benefits to competitive dermal filler products, that it will be competitive in price or gain acceptance in the marketplace.

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*® System upon entry to the U.S. market. The *LAP-BAND*® System also competes with surgical obesity procedures, including gastric bypass, vertical banded gastroplasty, sleeve gastrectomy, and biliopancreatic diversion.

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 a brimonidine product to compete with our *Alphagan® P* product. However, pursuant to our 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® P* have been converted to other brimonidine-containing products we market has increased to a specified threshold. In February 2007, we received a paragraph 4 Hatch-Waxman Act certification from Excela Pharmsci in which it purports to have sought FDA approval to market a generic brimonidine 0.15% ophthalmic solution.

Changes in the consumer marketplace and economic conditions may adversely affect sales or the profitability of our products.

Facial aesthetic products, such as *Botox*® Cosmetic and dermal fillers, obesity intervention products and, to a significant extent, breast implants, are products based on consumer choice. If we fail to anticipate, identify or react to competitive products or if consumer preferences in the cosmetic marketplace shift to alternative treatments, we may experience a decline in demand for these products. In addition, the popular media has at times in the past produced, and may continue in the future to produce, negative reports and publicity regarding the efficacy, safety or side effects of these products. Consumer perceptions of these products may be negatively impacted by these reports and for other reasons, including the use of unapproved botulinum toxins that result in injury, which may cause demand to decline.

Breast augmentations, *Botox*® Cosmetic and dermal fillers are also typically elective aesthetic procedures. Other than federally-mandated coverage and reimbursement for post-mastectomy reconstructive surgery, breast augmentations and other cosmetic procedures are not typically covered by insurance. Adverse changes in the economy may cause consumers to reassess their spending choices and reduce the demand for these procedures, and this shift could have an adverse effect on our sales and profitability.

Reimbursement for obesity surgery, including use of our products, is available to various degrees in most of our international markets. In the United States, coverage and reimbursement by insurance plans are increasing, but not widely available to all insured patients. Adverse changes in the economy could have an adverse effect on consumer spending and governmental health care resources. This shift could have an adverse effect on the sales and profitability of our obesity intervention business.

Changes in applicable tax laws may adversely affect sales or the profitability of *Botox*®, *Botox*® Cosmetic, our dermal fillers or breast implants. Because *Botox*® and *Botox*® Cosmetic are pharmaceutical products, we generally do not

collect or pay state sales or other tax on sales of *Botox*® or *Botox*® Cosmetic. We could be required to collect and pay state sales or other tax associated with prior, current or future years on sales of *Botox*® or *Botox*® Cosmetic, our dermal fillers or breast implants. In addition to any retroactive taxes and corresponding interest and penalties that could be assessed, if we were required to collect or pay state sales or other tax associated with current or future years on sales of *Botox*®, *Botox*® Cosmetic, our dermal fillers or breast implants, our sales of, or our profitability from, *Botox*®, *Botox*® Cosmetic, our dermal fillers or breast implants could be adversely affected due to the increased cost associated with those products.

We could experience difficulties obtaining or creating the raw materials needed to produce our products and interruptions in the supply of raw materials could disrupt our manufacturing and cause our sales and profitability to decline.

The loss of a material supplier or the interruption of our manufacturing processes could adversely affect our ability to manufacture or sell many of our products. We obtain the specialty chemicals that are the active pharmaceutical ingredients in certain of our products from single sources, who must maintain compliance with the FDA s cGMP regulations. If we experience difficulties acquiring sufficient quantities of these materials from our existing suppliers, or if our suppliers are found to be non-compliant with the cGMPs, obtaining the required regulatory approvals, including from the FDA or the European Medical Evaluation Agency (EMEA), to use alternative suppliers may be a lengthy and uncertain process. A lengthy interruption of the supply of one or more of these materials could adversely affect our ability to manufacture and supply products, which could cause our sales and profitability to decline. In addition, the manufacturing process to create the raw material necessary to produce *Botox*® is technically complex and requires significant lead-time. Any failure by us to forecast demand for, or to maintain an adequate supply of, the raw material and finished product could result in an interruption in the supply of *Botox*® and a resulting decrease in sales of the product.

We also rely on a single supplier for silicone raw materials used in some of our products, including breast implants. Although we have an agreement with this supplier to transfer the necessary formulations to us in the event that it cannot meet our requirements, we cannot guarantee that we would be able to produce or obtain a sufficient amount of quality silicone raw materials in a timely manner. We depend on third party manufacturers for silicone molded components. These third party manufacturers must maintain compliance with FDA s Quality System Regulation, or QSR, which sets forth the current good manufacturing practice standard for medical devices and requires manufacturers to follow design, testing and control documentation and air quality assurance procedures during the manufacturing process. Any material reduction in our raw material supply or a failure by our third party manufacturers to maintain compliance with the QSR could result in decreased sales of our products and a decease in our revenues. Additionally, certain of our manufacturing processes are only performed at one location worldwide.

Our future success depends upon our ability to develop new products, and new indications for existing products, that achieve regulatory approval for commercialization.

For our business model to be successful, we must continually develop, test and manufacture new products or achieve new indications for the use of our existing products. Prior to marketing, these new products and product indications must satisfy stringent regulatory standards and receive requisite approvals or clearances from regulatory authorities in the United States and abroad. The development, regulatory review and approval, and commercialization processes are time consuming, costly and subject to numerous factors that may delay or prevent the development, approval or clearance, and commercialization of new products, including legal actions brought by our competitors. To obtain approval or clearance of new indications or products in the United States, we must submit, among other information, the results of preclinical and clinical studies on the new indication or product candidate to the FDA. The number of preclinical and clinical studies that will be required for FDA approval varies depending on the new indication or product candidate, the disease or condition for which the new indication or product candidate is in development and the regulations applicable to that new indication or product candidate. Even if we believe that the data collected from clinical trials of new indications for our existing products or for our product candidates are promising, the FDA may find such data to be insufficient to support approval of the new indication or product. The FDA can delay, limit or deny approval of a new indication or product candidate for many reasons, including:

- a determination that the new indication or product candidate is not safe and effective;
- the FDA may interpret our preclinical and clinical data in different ways than we do;

the FDA may not approve our manufacturing processes or facilities;
the FDA may require us to perform post-marketing clinical studies; or
the FDA may change its approval policies or adopt new regulations.

Products that we are currently developing, other future product candidates or new indications for our existing products may or may not receive the regulatory approvals or clearances necessary for marketing or may receive such

approvals or clearances only after delay or unanticipated costs. Delays or unanticipated costs in any part of the process or our inability to obtain timely regulatory approval for our products, including those attributable to, among other things, our failure to maintain manufacturing facilities in compliance with all applicable regulatory requirements, including the cGMPs and QSR, could cause our operating results to suffer and our stock price to decrease. We are also required to pass pre-approval reviews and plant inspections of our and our suppliers facilities to demonstrate our compliance with the cGMPs and QSR.

Further, even if we receive FDA and other regulatory approvals for a new indication or product, the product may later exhibit adverse effects that limit or prevent its widespread use or that force us to withdraw the product from the market or to revise our labeling to limit the indications for which the product may be prescribed. In addition, even if we receive the necessary regulatory approvals, we cannot assure you that new products or indications will achieve market acceptance. Our future performance will be affected by the market acceptance of products such as *Lumigan*®, *Alphagan*® *P, Combigan*tm, for which we received an approvable letter from the FDA in December 2006, *Restasis*®, *Acular LS*®, *Zymar*®, *Botox*®, *Juvéderm*tm, *Ganfort*®, our *Lumigan*®/timolol combination, as well as silicone breast implant products, new indications for *Botox*® and new products such as *Posurdex*® and memantine. We cannot assure you that these or any other compounds or products that we are developing for commercialization will be approved by the FDA or foreign regulatory bodies for marketing or that we will be able to commercialize them on terms that will be profitable, or at all. If any of our products cannot be successfully or timely commercialized, our operating results could be materially adversely affected.

Our product development efforts may not result in commercial products.

We intend to continue an aggressive research and development program. Successful product development in the pharmaceutical and medical device industry is highly uncertain, and very few research and development projects produce a commercial product. Product candidates that appear promising in the early phases of development, such as in early human clinical trials, may fail to reach the market for a number of reasons, such as:

- the product candidate did not demonstrate acceptable clinical trial results even though it demonstrated positive preclinical trial results;
- the product candidate was not effective in treating a specified condition or illness;
- the product candidate had harmful side effects in humans or animals;
- the necessary regulatory bodies, such as the FDA, did not approve the product candidate for an intended use;
- the product candidate was not economical for us to manufacture and commercialize;
- other companies or people have or may have proprietary rights to the product candidate, such as patent rights, and will not let us sell it on reasonable terms, or at all;
- the product candidate is not cost effective in light of existing therapeutics or alternative devices; and
- certain of our licensors or partners may fail to effectively conduct clinical development or clinical manufacturing activities.

Several of our product candidates have failed or been discontinued at various stages in the product development process. Of course, there may be other factors that prevent us from marketing a product. We cannot guarantee we will be able to produce commercially successful products. Further, clinical trial results are frequently susceptible to varying interpretations by scientists, medical personnel, regulatory personnel, statisticians, and others, which may delay, limit, or prevent further clinical development or regulatory approvals of a product candidate. Also, the length of time that it takes for us to complete clinical trials and obtain regulatory approval for product marketing has in the past varied by product and by the intended use of a product. We expect that this will likely be the case with future product candidates and we cannot predict the length of time to complete necessary clinical trials and obtain regulatory approval.

If we are unable to obtain and maintain adequate protection for our intellectual property rights associated with the technologies incorporated into our products, our business and results of operations could suffer.

Our success depends in part on our ability to obtain patents or rights to patents, protect trade secrets and other proprietary technologies and processes, 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. Therefore, our future financial success may depend in part on obtaining patent protection for technologies incorporated into our products. We cannot assure you that such patents will be issued, or that any existing or future patents will be of commercial benefit. In addition, it is impossible to anticipate the breadth or degree of protection that any such patents will afford, and we cannot assure you that any such patents will not be successfully challenged in the future. If we are unsuccessful in obtaining or preserving patent protection, or if any of our products rely on unpatented proprietary technology, we cannot assure you that others will not commercialize products substantially identical to those products. Generic drug manufacturers are currently challenging the patents covering certain of our products, and we expect that they will continue to do so in the future.

We believe that the protection of our trademarks and service marks is an important factor in product recognition and in our ability to maintain or increase market share. If we do not adequately protect our rights in our various trademarks and service marks from infringement, their value to us could be lost or diminished, seriously impairing our competitive position. Moreover, the laws of certain foreign countries do not protect our intellectual property rights to the same extent as do the laws of the United States. 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 and proprietary information agreements with third parties, including our partners, customers, employees and consultants. These agreements may not provide meaningful protection or adequate remedies for violation of our rights in the event of unauthorized use or disclosure of confidential information. It is possible that these agreements will be breached or that they will not be enforceable in every instance, and that we will 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.

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, could be substantial and can preclude or delay commercialization of products. Such litigation also could require a substantial commitment of our management s time. For certain of our product candidates, third parties may have patents or pending patents that they claim prevent us from commercializing certain product candidates in certain territories. Our success depends in part on our ability to obtain and defend patent rights and other intellectual property rights that are important to the commercialization of our products and product candidates. For additional information on our material patents, see Patents, Trademarks and Licenses in Item 1 of Part I of this report, Business.

We may be subject to intellectual property litigation and infringement claims, which could cause us to incur significant expenses and losses or prevent us from selling our products.

We cannot assure you that our products will not infringe patents or other intellectual property rights held by third parties. In the event we discover that we may be infringing third party patents or other intellectual property rights, we may not be able to obtain licenses from those third parties on commercially attractive terms or at all. We may have to defend, and have defended, against charges that we violated patents or the proprietary rights of third parties. Litigation is costly and time-consuming, and diverts the attention of our management and technical personnel. In addition, if we infringe the intellectual property rights of others, we could lose our right to develop, manufacture or sell products or could be required to pay monetary damages or royalties to license proprietary rights from third parties. An adverse determination in a judicial or administrative proceeding or a failure to obtain necessary licenses could prevent us from manufacturing or selling our products, which could harm our business, financial condition, prospects, results of operations and cash flows. 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.

Importation of products from Canada and other countries into the United States and intra-European Union trade may lower the prices we receive for our products.

In the United States, some of our pharmaceutical products are subject to competition from lower priced versions of those products and competing products from Canada, Mexico and other countries where government price controls or other market dynamics result in lower prices. Our products that require a prescription in the United States are often available to consumers in these other markets without a prescription, which may cause consumers to further seek out our products in these lower priced markets. The ability of patients and other customers to obtain these lower priced imports has grown significantly as a result of the Internet, an expansion of pharmacies in Canada and elsewhere targeted to American purchasers, the increase in U.S.-based businesses affiliated with Canadian pharmacies marketing to American purchasers, and other factors. These foreign imports are illegal under current U.S. law, with the sole exception of limited quantities of prescription drugs imported for personal use. However, the volume of imports continues to rise due to the limited enforcement resources of the FDA and the U.S. Customs Service, and there is increased political pressure to permit the imports as a mechanism for expanding access to lower priced medicines.

In December 2003, Congress enacted the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. This law contains provisions that may change U.S. import laws and expand consumers ability to import lower priced versions of our products and competing products from Canada, where there are government price controls. These changes to U.S. import laws will not take effect unless and until the Secretary of Health and Human Services certifies that the changes will lead to substantial savings for consumers and will not create a public health safety issue. The Secretary of Health and Human Services has not made such a certification. However, it is possible that the current Secretary or a subsequent Secretary could make such a certification in the future. As directed by Congress, a task force on drug importation conducted a comprehensive study regarding the circumstances under which drug importation could be safely conducted and the consequences of importation on the health, medical costs and development of new medicines for U.S. consumers. The task force issued its report in December 2004, finding that there are significant safety and economic issues that must be addressed before importation of prescription drugs is permitted. In addition, federal legislative proposals have been made to implement the changes to the U.S. import laws without any certification, and to broaden permissible imports in other ways. Even if the changes to the U.S. import laws do not take effect, and other changes are not enacted, imports from Canada and elsewhere may continue to increase due to market and political forces, and the limited enforcement resources of the FDA, the U.S. Customs Service and other government agencies. For example, Public Law Number 109-295, which was signed into law in October 2006 and provides appropriations for the Department of Homeland Security for the 2007 fiscal year, expressly prohibits the U.S. Customs Services from using funds to prevent individuals from importing from Canada less than a 90-day supply of a prescription drug for personal use, when the drug otherwise complies with the Federal Food, Drug and Cosmetic Act. A bipartisan group of U.S. Senators also recently introduced The Pharmaceutical Market and Drug Safety Act of 2007, which, as proposed, would permit the importation of lower cost prescription drugs by FDA-approved foreign pharmacies, and U.S. licensed pharmacies and wholesalers. Further, certain state and local governments have implemented importation schemes for their citizens, and, in the absence of federal action to curtail such activities, we expect other states and local governments to launch importation efforts.

The importation of foreign products adversely affects our profitability in the United States. This impact could become more significant in the future, and the impact could be even greater if there is a further change in the law or if state or local governments take further steps to import products from abroad.

Our business will continue to expose us to risks of environmental liabilities.

Our product development programs and manufacturing processes involve the controlled use of hazardous materials, chemicals and toxic compounds. These programs and processes expose us to risks that an accidental contamination

could lead to noncompliance with environmental laws, regulatory enforcement actions and claims for personal injury and property damage. If an accident or environmental discharge occurs, or if we discover contamination caused by prior operations, including by prior owners and operators of properties we acquire, we could be liable for cleanup obligations, damages and fines. The substantial unexpected costs we may incur could have a significant and adverse effect on our business and results of operations.

We may experience losses due to product liability claims, product recalls or corrections.

The design, development, manufacture and sale of our products involve an inherent risk of product liability or other claims by consumers and other third parties. We have in the past been, and continue to be, subject to various product liability claims and lawsuits. In addition, we have in the past and may in the future recall or issue field corrections related to our products due to manufacturing deficiencies, labeling errors or other safety or regulatory reasons. We cannot assure you that we will not in the future experience material losses due to product liability claims, lawsuits, product recalls or corrections.

We have assumed Inamed s product liability risks, including any product liability for its past and present manufacturing of breast implant products. The manufacture and sale of breast implant products entails significant risk of product liability claims due to potential allegations of possible disease causation, transmission, complications and other health factors, rupture, deflation or other product failure. 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 products liability litigation. Historically, other breast implant manufacturers that suffered such claims in the 1990 s were forced to cease operations or even to declare bankruptcy.

Additionally, recent FDA marketing approval for our silicone breast implants requires that we monitor patients in our core study out to 10 years if there has been explantation without replacement; patients in the core study receive MRI s at seven and nine years; we conduct a large, 10 year postapproval study; and we conduct additional smaller studies, including a study aimed at ensuring patients are adequately informed about the risks of our silicone breast implants and that the format and content of patient labeling is adequate. Our competitor, Mentor, is similarly required to conduct such postapproval studies. We are seeking marketing approval for other silicone breast implants in the United States, and if we obtain this approval, it may similarly be subject to significant restrictions and requirements, including the need for a patient registry, follow up MRI s, and substantial Phase IV clinical trial commitments.

We also face a substantial risk of product liability claims from our eye care, neuromodulator and skin care products and may face similar risks associated with our obesity intervention and facial aesthetics products. Additionally, our pharmaceutical and medical device products may cause, or may appear to cause, serious adverse side effects or potentially dangerous drug interactions if misused or improperly prescribed. We are subject to adverse event reporting regulations that require us to report to the FDA or similar bodies in other countries if our products are associated with a death or serious injury. These adverse events, among others, could result in additional regulatory controls, such as the performance of costly post-approval clinical studies or revisions to our approved labeling, which could limit the indications or patient population for our products or could even lead to the withdrawal of a product from the market. Furthermore, any adverse publicity associated with such an event could cause consumers to seek alternatives to our products, which may cause our sales to decline, even if our products are ultimately determined not to have been the primary cause of the event.

Negative publicity concerning the safety of our products may harm our sales and we may be forced to withdraw products.

Physicians and potential and existing patients may have a number of concerns about the safety of our products, including *Botox*®, breast implants, eye care pharmaceuticals, skin care products, obesity intervention products and facial dermal fillers, whether or not such concerns have a basis in generally accepted science or peer-reviewed scientific research. Negative publicity whether accurate or inaccurate about our products, based on, for example, news about *Botox*®, breast implant litigation, regulatory activities and developments, or bovine spongiform encephalopathy (BSE) or Creutzfeld-Jacob, or mad cow disease, whether involving us or a competitor, or new

government regulation, could materially reduce market acceptance of our products and could result in product withdrawals. In addition, significant negative publicity could result in an increased number of product liability claims, whether or not these claims have a basis in scientific fact. Furthermore, any adverse publicity associated with such an event could cause consumers to seek alternatives to our products, which may cause our sales to decline, even if our products are ultimately determined not to have been the primary cause of the event.

Health care initiatives and other third-party payor cost-containment pressures could cause us to sell our products at lower prices, resulting in decreased revenues.

Some of our products are purchased or reimbursed by state and federal government authorities, private health insurers and other organizations, such as health maintenance organizations, or HMOs, and managed care organizations, or MCOs. Third party payors increasingly challenge pharmaceutical and other medical device product pricing. There also continues to be a trend toward managed healthcare in the United States. Pricing pressures by third-party payors and the growth of organizations such as HMOs and MCOs could result in lower prices and/or a reduction in demand for our products.

In addition, legislative proposals and enactments to reform healthcare and government insurance programs, including the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or MMA, and the Deficit Reduction Act of 2005, or DRA, could significantly influence the manner in which pharmaceutical products and medical devices are prescribed and purchased. For example, effective January 1, 2006, the MMA established a new Medicare outpatient prescription drug benefit under Part D. The MMA also established a competitive acquisition program, or CAP, in which physicians who administer drugs in their offices are offered an option to acquire drugs covered under the Medicare Part B benefit from vendors who are selected in a competitive bidding process. Implementation of the CAP began in July 2006. Further, the DRA requires the Centers for Medicare and Medicaid Services to amend certain formulas used to calculate pharmacy reimbursement under Medicaid. These changes could lead to reduced payments to pharmacies for certain pharmaceutical products. Such cost containment measures and healthcare reforms could adversely affect our ability to sell our products.

Furthermore, individual states have become increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access, and to encourage importation from other countries and bulk purchasing. Legally-mandated price controls on payment amounts by third-party payors or other restrictions could negatively and materially impact our revenues and financial condition. We encounter similar regulatory and legislative issues in most countries outside the United States.

We expect there will continue to be federal and state laws and/or regulations, proposed and implemented, that could limit the amounts that foreign, federal and state governments will pay for health care products and services. The extent to which future legislation or regulations, if any, relating to the health care industry or third-party coverage and reimbursement may be enacted or what effect such legislation or regulation would have on our business remains uncertain. Such measures or other health care system reforms that are adopted could have a material adverse effect on our ability to successfully commercialize our products or could limit or eliminate our spending on development projects and affect our ultimate profitability.

In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical and medical device products and which suppliers will be included in their prescription drug and other health care programs. This can reduce demand for our products or put pressure on our product pricing, which could negatively affect our revenues and profitability.

We are subject to risks arising from currency exchange rates, which could increase our costs and may cause our profitability to decline.

We collect and pay a substantial portion of our sales and expenditures in currencies other than the U.S. dollar. Therefore, fluctuations in foreign currency exchange rates affect our operating results. We cannot assure you that future exchange rate movements, inflation or other related factors will not have a material adverse effect on our sales

or operating expenses.

We are subject to risks associated with doing business internationally.

Our business is subject to certain risks inherent in international business, many of which are beyond our control. These risks include, among other things:

- adverse changes in tariff and trade protection measures;
- unexpected changes in foreign regulatory requirements, including quality standards and other certification requirements;
- potentially negative consequences from changes in or interpretations of tax laws;
- differing labor regulations;
- changing economic conditions in countries where our products are sold or manufactured or in other countries;
- differing local product preferences and product requirements;
- exchange rate risks;
- restrictions on the repatriation of funds;
- political unrest and hostilities;
- product liability, intellectual property and other claims;
- new export license requirements;
- differing degrees of protection for intellectual property; and
- difficulties in coordinating and managing foreign operations.

Any of these factors, or any other international factors, could have a material adverse effect on our business, financial condition and results of operations. We cannot assure you that we can successfully manage these risks or avoid their effects.

The consolidation of drug wholesalers and other wholesaler actions could increase competitive and pricing pressures on pharmaceutical manufacturers, including us.

We sell our pharmaceutical products primarily through wholesalers. These wholesale customers comprise a significant part of the distribution network for pharmaceutical products in the United States. This distribution network is continuing to undergo significant consolidation marked by mergers and acquisitions. As a result, a smaller number of large wholesale distributors control a significant share of the market. We expect that consolidation of drug wholesalers will increase competitive and pricing pressures on pharmaceutical manufacturers, including us. In addition, wholesalers may apply pricing pressure through fee-for-service arrangements, and their purchases may exceed customer demand, resulting in reduced wholesaler purchases in later quarters. We cannot assure you that we can manage these pressures or that wholesaler purchases will not decrease as a result of this potential excess buying.

Our failure to attract and retain key managerial, technical, selling and marketing personnel could adversely affect our business.

Our success depends upon our retention of key managerial, technical, selling and marketing personnel. The loss of the services of key personnel might significantly delay or prevent the achievement of our development and strategic objectives.

We must continue to attract, train and retain managerial, technical, selling and marketing personnel. Competition for such highly skilled employees in our industry is high, and we cannot be certain that we will be successful in recruiting or retaining such personnel. We also believe that our success depends to a significant extent on the ability of our key personnel to operate effectively, both individually and as a group. If we are unable to identify, hire and integrate new employees in a timely and cost-effective manner, our operating results may suffer.

We may acquire companies in the future and these acquisitions could disrupt our business.

As part of our business strategy, we regularly consider and, as appropriate, make acquisitions of technologies, products and businesses that we believe are complementary to our business. Acquisitions typically entail many risks and could result in difficulties in integrating the operations, personnel, technologies and products of the companies

acquired, some of which may result in significant charges to earnings. If we are unable to successfully integrate our acquisitions with our existing business, we may not obtain the advantages that the acquisitions were intended to create, which may materially adversely affect our business, results of operations, financial condition and cash flows, our ability to develop and introduce new products and the market price of our stock. In connection with acquisitions, we could experience disruption in our business or employee base, or key employees of companies that we acquire may seek employment elsewhere, including with our competitors. Furthermore, the products of companies we acquire may overlap with our products or those of our customers, creating conflicts with existing relationships or with other commitments that are detrimental to the integrated businesses.

Uncertainties exist in integrating the business and operations of Inamed and Cornéal into our own.

We are currently integrating certain of Inamed s and Cornéal s functions and operations into our own, although there can be no assurance that we will be successful in this endeavor. There are inherent challenges in integrating the operations that could result in a delay or the failure to achieve the anticipated synergies and, therefore, any potential cost savings and increases in earnings. Issues that must be addressed in integrating the operations of Inamed and Cornéal into our own include, among other things:

- conforming standards, controls, procedures and policies, business cultures and compensation structures between the companies;
- conforming information technology and accounting systems;
- consolidating corporate and administrative infrastructures;
- consolidating sales and marketing operations;
- retaining existing customers and attracting new customers;
- retaining key employees;
- identifying and eliminating redundant and underperforming operations and assets;
- minimizing the diversion of management s attention from ongoing business concerns;
- separating the facial aesthetics and ophthalmic surgical businesses of Cornéal and executing the divesture of the ophthalmic surgical business;
- coordinating geographically dispersed organizations;
- managing tax costs or inefficiencies associated with integrating the operations of the combined company; and
- making any necessary modifications to operating control standards to comply with the Sarbanes-Oxley Act of 2002 and the rules and regulations promulgated thereunder.

If we are not able to adequately address these challenges, we may not realize the anticipated benefits of the integration of the companies. Actual cost and sales synergies, if achieved at all, may be lower than we expect and may take longer to achieve than we anticipate.

Compliance with the extensive government regulations to which we are subject is expensive and time consuming, and may result in the delay or cancellation of product sales, introductions or modifications.

Extensive industry regulation has had, and will continue to have, a significant impact on our business, especially our product development and manufacturing capabilities. All companies that manufacture, market and distribute pharmaceuticals and medical devices, including us, are subject to extensive, complex, costly and evolving regulation by federal governmental authorities, principally by the FDA and the U.S. Drug Enforcement Administration, or DEA, and similar foreign and state government agencies. Failure to comply with the regulatory requirements of the FDA, DEA and other U.S. and foreign regulatory agencies may subject a company to administrative or judicially imposed sanctions, including, among others, a refusal to approve a pending application to market a new product or a new indication for an existing product. The Federal Food, Drug, and Cosmetic Act, the Controlled Substances Act and other domestic and foreign statutes and regulations govern or influence the research, testing, manufacturing, packing,

labeling, storing, record keeping, safety, effectiveness, approval, advertising, promotion, sale and distribution of our products. Under certain of these regulations, we are subject to periodic inspection of our facilities, production processes and control operations and/or the testing of our products by the FDA, the DEA and other authorities, to confirm that we are in compliance with all applicable

regulations, including FDA cGMP regulations with respect to drug and biologic products and the QSR with respect to medical device products. The FDA conducts pre-approval and post-approval reviews and plant inspections of us and our suppliers to determine whether our record keeping, production processes and controls, personnel and quality control are in compliance with the cGMPs, the QSR and other FDA regulations. We are also required to perform extensive audits of our vendors, contract laboratories and suppliers to ensure that they are compliant with these requirements. In addition, in order to commercialize our products or new indications for an existing product, we must demonstrate that the product or new indication is safe and effective, and that our and our suppliers manufacturing facilities are compliant with applicable regulations, to the satisfaction of the FDA and other regulatory agencies.

The process for obtaining governmental approval to manufacture and to commercialize pharmaceutical and medical device products is rigorous, typically takes many years and is costly, and we cannot predict the extent to which we may be affected by legislative and regulatory developments. We are dependent on receiving FDA and other governmental approvals prior to manufacturing, marketing and distributing our products. We may fail to obtain approval from the FDA or other governmental authorities for our product candidates, or we may experience delays in obtaining such approvals, due to varying interpretations of data or our failure to satisfy rigorous efficacy, safety and manufacturing quality standards. Consequently, there is always a risk that the FDA or other applicable governmental authorities will not approve our products, or will take post-approval action limiting or revoking our ability to sell our products, or that the rate, timing and cost of such approvals will adversely affect our product introduction plans, results of operations and stock price. Despite the time and expense exerted, regulatory approval is never guaranteed.

Even after we obtain regulatory approval for a product candidate or new indication, we are subject to extensive regulation, including ongoing compliance with the FDA s cGMP and QSR regulations, completion of post-marketing clinical studies mandated by the FDA, and compliance with regulations relating to labeling, advertising, marketing and promotion. In addition, we are subject to adverse event reporting regulations that require us to report to the FDA if our products are associated with a death or serious injury. If we or any third party that we involve in the testing, packing, manufacture, labeling, marketing and distribution of our products fail to comply with any such regulations, we may be subject to, among other things, warning letters, product seizures, recalls, fines or other civil penalties, injunctions, suspension or revocation of approvals, operating restrictions and/or criminal prosecution. The FDA recently has increased its enforcement activities related to the advertising and promotion of pharmaceutical, biological and medical device products. In particular, the FDA has expressed concern regarding the pharmaceutical industry s compliance with the agency s regulations and guidance governing direct-to-consumer advertising, and has increased its scrutiny of such promotional materials. The FDA may limit or, with respect to certain products, terminate our dissemination of direct-to-consumer advertisements in the future, which could cause sales of those products to decline. Physicians may prescribe pharmaceutical and biologic products, and utilize medical device products for uses that are not described in a product s labeling or differ from those tested by us and approved by the FDA. While such off-label uses are common and the FDA does not regulate a physician s choice of treatment, the FDA does restrict a manufacturer s communications on the subject of off-label use. Companies cannot actively promote FDA-approved pharmaceutical, biologic or medical device products for off-label uses, but they may disseminate to physicians articles published in peer-reviewed journals. To the extent allowed by law, we disseminate peer-reviewed articles on our products to targeted physicians. If, however, our promotional activities fail to comply with the FDA s or another regulatory body s regulations or guidelines, we may be subject to warnings from, or enforcement action by, the FDA or another enforcement agency.

From time to time, legislative or regulatory proposals are introduced that could alter the review and approval process relating to our products. It is possible that the FDA or other governmental authorities will issue additional regulations further restricting the sale of our present or proposed products. Any change in legislation or regulations that govern the review and approval process relating to our current and future products could make it more difficult and costly to obtain approval for new products, or to produce, market, and distribute existing products.

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If we market products in a manner that violates health care fraud and abuse laws, we may be subject to civil or criminal penalties.

The Federal health care program anti-kickback statute prohibits, among other things, knowingly and willfully offering, paying, soliciting, or receiving remuneration to induce or in return for purchasing, leasing, ordering, or arranging for the purchase, lease or order of any health care item or service reimbursable under Medicare, Medicaid or other federally financed health care programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers, on the one hand, and prescribers, purchasers and formulary managers, on the other hand. Although there are a number of statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution, the exemptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exemption or safe harbor.

Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to get a false claim paid. Pharmaceutical companies have been prosecuted under these laws for a variety of alleged promotional and marketing activities, such as allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product; reporting to pricing services inflated average wholesale prices that were then used by federal programs to set reimbursement rates; engaging in off-label promotion that caused claims to be submitted to Medicaid for non-covered off-label uses; and submitting inflated best price information to the Medicaid Rebate Program.

HIPAA created two new federal crimes: health care fraud, and false statements relating to health care matters. The health care fraud statute prohibits knowingly and willfully executing a scheme to defraud any health care benefit program, including private payors. The false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for health care benefits, items or services.

The majority of states also have statutes or regulations similar to these federal laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. In addition, some states have laws that require pharmaceutical companies to adopt comprehensive compliance programs. For example, under California law, pharmaceutical companies must comply with both the April 2003 Office of Inspector General Compliance Program Guidance for Pharmaceutical Manufacturers and the July 2002 PhRMA Code on Interactions with Healthcare Professionals. We have adopted and implemented a compliance program which we believe satisfies the requirements of California law.

Sanctions under these federal and state laws may include civil monetary penalties, exclusion of a manufacturer s products from reimbursement under government programs, criminal fines and imprisonment. Because of the breadth of these laws and the narrowness of the safe harbors, it is possible that some of our business activities could be subject to challenge under one or more of such laws. For example, we and several other pharmaceutical companies are currently subject to suits by governmental entities in several jurisdictions, including Erie, Oswego and Schenectady Counties in New York and in Alabama alleging that we and these other companies, through promotional, discounting and pricing practices, reported false and inflated average wholesale prices or wholesale acquisition costs and failed to report best prices as required by federal and state rebate statutes, resulting in the plaintiffs overpaying for certain medications. If our past or present operations are found to be in violation of any of the laws described above or other similar governmental regulations to which we are subject, we may be subject to the applicable penalty associated with the violation which could adversely affect our ability to operate our business and our financial results.

If our collaborative partners do not perform, we will be unable to develop and market products as anticipated.

We have entered into collaborative arrangements with third parties to develop and market certain products, including our arrangement with GlaxoSmithKline to market *Botox*® in Japan and China and certain other products in the United States. We cannot assure you that these collaborations will be successful, lead to significant sales of our products in our partners territories or lead to the creation of additional products. If we fail to maintain our

existing collaborative arrangements or fail to enter into additional collaborative arrangements, our licensing revenues and/or the number of products from which we could receive future revenues could decline.

Our dependence on collaborative arrangements with third parties subjects us to a number of risks. These collaborative arrangements may not be on terms favorable to us. Agreements with collaborative partners typically allow partners significant discretion in marketing our products or electing whether or not to pursue any of the planned activities. We cannot fully control the amount and timing of resources our collaborative partners may devote to products based on the collaboration, and our partners may choose to pursue alternative products to the detriment of our collaboration. In addition, our partners may not perform their obligations as expected. Business combinations, significant changes in a collaborative partner s business strategy, or its access to financial resources may adversely affect a partner s willingness or ability to complete its obligations. Moreover, we could become involved in disputes with our partners, which could lead to delays or termination of the collaborations and time-consuming and expensive litigation or arbitration. Even if we fulfill our obligations under a collaborative agreement, our partner can terminate the agreement under certain circumstances. If any collaborative partners were to terminate or breach our agreements with them, or otherwise fail to complete their obligations in a timely manner, we could be materially and adversely affected.

Unanticipated changes in our tax rates or exposure to additional income tax liabilities could affect our profitability.

We are subject to income taxes in both the United States and numerous foreign jurisdictions. Our effective tax rate could be adversely affected by changes in the mix of earnings in countries with different statutory tax rates, changes in the valuation of deferred tax assets and liabilities, changes in or interpretations of tax laws, including pending tax law changes, changes in our manufacturing activities and changes in our future levels of research and development spending. In addition, we are subject to the continuous examination of our income tax returns by the Internal Revenue Service and other state and foreign tax authorities. We regularly assess the likelihood of outcomes resulting from these examinations to determine the adequacy of our estimated income tax liabilities. There can be no assurance that the outcomes from these continuous examinations will not have an adverse effect on our provision for income taxes and estimated income tax liabilities.

The terms of our debt agreements impose many restrictions on us. Failure to comply with these restrictions could result in acceleration of our substantial debt. Were this to occur, we might not have, or be able to obtain, sufficient cash to pay our accelerated indebtedness.

Our total indebtedness as of December 31, 2006 was approximately $1,708.4 million. This indebtedness may limit our flexibility in planning for, or reacting to, changes in our business and the industry in which it operates and, consequently, place us at a competitive disadvantage to our competitors. The operating and financial restrictions and covenants in our debt agreements may adversely affect our ability to finance future operations or capital needs or to engage in new business activities. For example, our debt agreements restrict our ability to, among other things:

incur liens or engage in sale lease-back transactions; and
engage in consolidations, mergers, and asset sales.

In addition, our debt agreements include financial covenants that we maintain certain financial ratios. As a result of these covenants and ratios, we have certain limitations on the manner in which we can conduct our business, and we may be restricted from engaging in favorable business activities or financing future operations or capital needs. Accordingly, these restrictions may limit our ability to successfully operate our business. Failure to comply with the financial covenants or to maintain the financial ratios contained in our debt agreements could result in an event of default that could trigger acceleration of our indebtedness. We cannot assure you that our future operating results will be sufficient to ensure compliance with the covenants in our debt agreements or to remedy any such default. In addition, in the event of any default and related acceleration of obligations, we may not have or be able to obtain

sufficient funds to make any accelerated payments.

Litigation may harm our business or otherwise distract our management.

Substantial, complex or extended litigation could cause us to incur large expenditures and distract our management. For example, lawsuits by employees, stockholders, customers or competitors could be very costly and substantially disrupt our business. Disputes from time to time with such companies or individuals are not uncommon, and we cannot assure you that that we will always be able to resolve such disputes out of court or on terms favorable to us.

Our publicly-filed SEC reports are reviewed by the SEC from time to time and any significant changes required as a result of any such review may result in material liability to us and have a material adverse impact on the trading price of our common stock.

The reports of publicly-traded companies are subject to review by the Securities and Exchange Commission from time to time for the purpose of assisting companies in complying with applicable disclosure requirements and to enhance the overall effectiveness of companies public filings, and comprehensive reviews of such reports are now required at least every three years under the Sarbanes-Oxley Act of 2002. SEC reviews may be initiated at any time. While we believe that our previously filed SEC reports comply, and we intend that all future reports will comply in all material respects with the published rules and regulations of the SEC, we could be required to modify or reformulate information contained in prior filings as a result of an SEC review. Any modification or reformulation of information contained in such reports could be significant and could result in material liability to us and have a material adverse impact on the trading price of our common stock.

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

None.

Item 2. ***Properties***

Our operations are conducted in owned and leased facilities located throughout the world. We believe our present facilities are adequate for our current needs. Our headquarters and primary administrative and research facilities, which we own, are located in Irvine, California. We lease additional facilities in California to provide administrative, research and raw material support, manufacturing, warehousing and distribution. We own one facility in Texas for manufacturing and warehousing.

Outside of the United States, we own, lease and operate various facilities for manufacturing and warehousing. Those facilities are located in Brazil, France, Ireland, Poland and Costa Rica. Other material facilities include leased facilities for administration in Australia, Brazil, Canada, France, Germany, Hong Kong, Ireland, Italy, Japan, Spain and the United Kingdom.

Item 3. ***Legal Proceedings***

The information required by this Item is incorporated herein by reference to Note 12, Commitments and Contingencies, in our notes to the consolidated financial statements listed under Item 15 of Part IV of this report, Exhibits and Financial Statement Schedules.

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

We did not submit any matter during the fourth quarter of the fiscal year covered by this report to a vote of security holders, through the solicitation of proxies or otherwise.

PART II

Item 5. ***Market For Registrant s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities***

The following table shows the quarterly price range of our common stock and the cash dividends declared per share of common stock during the periods listed.

	2006			2005		
Calendar Quarter	**Low**	**High**	**Div.**	**Low**	**High**	**Div.**
First	$ 105.02	$ 117.99	$ 0.10	$ 69.60	$ 81.16	$ 0.10
Second	92.57	109.31	0.10	69.01	86.29	0.10
Third						