ALLERGAN INC
Form 10-K
February 26, 2010
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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, 2009

or

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

Commission File Number 1-10269

Allergan, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**95-1622442**
(State or Other Jurisdiction of Incorporation or Organization)	(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, Including Area Code)

Securities Registered Pursuant to Section 12(b) of the Act:

Title of Each Class	**Name of Each Exchange on Which 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 ¨

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ¨ No 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 ¨

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes þ No ¨

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant s knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ¨

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

Large accelerated filer þ	Accelerated filer ¨
Non-accelerated filer ¨ (Do not check if a smaller reporting company)	Smaller reporting company ¨

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

As of June 30, 2009, the aggregate market value of the registrant s common stock held by non-affiliates of the registrant was approximately $14,430 million based on the closing sale price as reported on the New York Stock Exchange.

Common stock outstanding as of February 19, 2010 307,511,888 shares (including 3,511,177 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 April 29, 2010, which proxy statement will be filed no later than 120 days after the close of the registrant s fiscal year ended December 31, 2009.

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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 or the negative 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 multi-specialty health care company focused on developing and commercializing innovative pharmaceuticals, biologics and medical devices that enable people to live life to its greatest potential to see more clearly, move more freely and express themselves more fully. Our diversified approach enables us to follow our research and development into new specialty areas where unmet needs are significant.

We discover, develop and commercialize specialty pharmaceutical, medical device and over-the-counter products for the ophthalmic, neurological, medical aesthetics, medical dermatology, breast aesthetics, obesity intervention, urological and other specialty markets in more than 100 countries around the world. Our diversified business model includes products for which consumers may be eligible for reimbursement and cash pay products that consumers pay for directly. Based on internal information and assumptions, we estimate that in fiscal year 2009, approximately 72% of our net product sales were derived from reimbursable products and 28% of our net product sales were derived from cash pay products.

We are a pioneer in specialty pharmaceutical, biologic and medical device research and development, with global efforts targeting products and technologies related to eye care, skin care, neuromodulators, medical aesthetics, obesity intervention, urology and neurology. In 2009, our research and development expenditures were approximately 15.9% of our product net sales or approximately $706.0 million. 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.

In March 2006, we acquired Inamed Corporation, or Inamed, a global health care manufacturer and marketer of breast implants, a range of dermal filler products to correct facial wrinkles, and bariatric medical devices for approximately $3.3 billion, consisting of approximately $1.4 billion in cash and 34,883,386 shares of our common stock.

In the first quarter of 2007, we acquired Groupe Cornéal Laboratoires, or Cornéal, a health care company that develops, manufactures and markets dermal fillers, for approximately $209.2 million, net of cash acquired. The acquisition of Cornéal expanded our marketing rights to *Juvéderm*® 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 research and development of *Juvéderm*® and other dermal fillers.

In the fourth quarter of 2007, we acquired Esprit Pharma Holding Company, Inc., or Esprit, for approximately $370.8 million, net of cash acquired. By acquiring Esprit, we obtained an exclusive license to

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market *Sanctura*® (trospium chloride), or *Sanctura*®, and *Sanctura XR*® (trospium chloride extended release capsules), or *Sanctura XR*®, anticholinergics approved for the treatment of overactive bladder, or OAB, in the United States and its territories from Indevus Pharmaceuticals, Inc., or Indevus. We launched *Sanctura XR*® in the United States in the first quarter of 2008. In the second quarter of 2008, we entered into a license agreement with Indevus and Madaus GmbH, which grants us the right to seek approval for and to commercialize *Sanctura XR*® in Canada. In the first quarter of 2010, Health Canada, the Canadian national regulatory body, approved *Sanctura XR*®.

In the third quarter of 2008, we acquired *Aczone*® (dapsone) gel 5% from QLT USA, Inc., or QLT, a wholly-owned subsidiary of QLT Inc. for approximately $150 million. *Aczone*®, approved for sale in both the United States and Canada, is indicated for the treatment of acne vulgaris in patients 12 and older. *Aczone*® contains the first new FDA-approved chemical entity (dapsone) for acne treatment since *Tazorac*® (tazarotene) gel was approved in 1997. We launched *Aczone*® in the United States in the fourth quarter of 2008.

In the fourth quarter of 2008, we entered into a strategic collaboration arrangement with Spectrum Pharmaceuticals, Inc., or Spectrum, to develop and commercialize apaziquone, an antineoplastic agent currently being investigated for the treatment of non-muscle invasive bladder cancer by intravesical instillation. Under the collaboration, Spectrum is conducting two Phase 3 clinical trials to explore apaziquone s safety and efficacy as a potential treatment for non-muscle invasive bladder cancer following surgery. We made an initial payment of $41.5 million to Spectrum and will make additional payments of up to $304 million based on the achievement of certain development, regulatory and commercialization milestones. Spectrum retained exclusive rights to apaziquone in Asia, including Japan and China. Allergan received exclusive rights to apaziquone for the treatment of bladder cancer in the rest of the world, including the United States, Canada and Europe. In the United States, Allergan and Spectrum will co-promote apaziquone and share in its profits and expenses. Allergan will also pay Spectrum royalties on all of its apaziquone sales outside of the United States. In the third quarter of 2009, the U.S. Food and Drug Administration, or FDA, granted Fast Track Designation for the investigation of apaziquone for the treatment of non-muscle invasive bladder cancer. Fast Track Designation was designed to facilitiate drug development and expedite the review of drugs intended to treat serious conditions. In the fourth quarter of 2009, Spectrum completed enrollment in the two Phase 3 clinical trials.

In the third quarter of 2009, we entered into a co-promotion agreement with Quintiles Transnational Corp., or Quintiles, under which Quintiles will co-promote *Sanctura XR*®, *Latisse*® and *Aczone*®, generally targeting primary care physicians. We will continue to promote *Sanctura XR*®, *Latisse*® and *Aczone*® using our existing sales forces to specialty physicians.

In the first quarter of 2010, we acquired Serica Technologies, Inc., a medical device company focused on the development of biodegradable silk-based scaffolds for use in tissue regeneration, including breast augmentation, revision and reconstruction and bariatric applications, for an aggregate purchase price of approximately $70.0 million.

We were founded in 1950 and incorporated in Delaware in 1977. Our principal executive offices are located at 2525 Dupont Drive, Irvine, California, 92612, and our telephone number at that location is (714) 246-4500. Our Internet website address is *www.allergan.com*[1]. 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, or SEC. The SEC maintains an Internet site at *www.sec.gov* that contains the reports, proxy and information statements and other information that we file electronically with the SEC.

Operating Segments

We operate 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 chronic dry eye, glaucoma therapy, ocular inflammation, infection, allergy and retinal

[1] This website address is not intended to function as a hyperlink and the information at this website address is not incorporated by reference into this Annual Report on Form 10-K.

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diseases; *Botox*® for certain therapeutic and aesthetic indications; skin care products for acne, psoriasis, other prescription and over-the-counter skin care products and, beginning in the first quarter of 2009, eyelash growth products; and, beginning in the fourth quarter of 2007 urologics products. The medical devices segment produces a broad range of medical devices, including: breast implants for augmentation, revision and reconstructive surgery; obesity intervention products, including the *Lap-Band*® System and the *Orbera* Intragastric Balloon System and facial aesthetics products. The following table sets forth, for the periods indicated, product net sales for each of our product lines within our specialty pharmaceuticals segment and 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,		
	2009	2008	2007
	(dollars in millions)		
Specialty Pharmaceuticals Segment Product Net Sales by Product Line			
Eye Care Pharmaceuticals	$ 2,100.6	$ 2,009.1	$ 1,776.5
Botox®/Neuromodulator	1,309.6	1,310.9	1,211.8
Skin Care Products	208.0	113.7	110.7
Urologics	65.6	68.6	6.0
Total Specialty Pharmaceuticals Segment Product Net Sales	$ 3,683.8	$ 3,502.3	$ 3,105.0
Specialty Pharmaceuticals Segment Product Net Sales			
Domestic	66.5%	65.2%	65.8%
International	33.5%	34.8%	34.2%
Medical Devices Segment Product Net Sales by Product Line			
Breast Aesthetics	$ 287.5	$ 310.0	$ 298.4
Obesity Intervention	258.2	296.0	270.1
Facial Aesthetics	218.1	231.4	202.8
Core Medical Devices	763.8	837.4	771.3
Other (1)			2.7
Total Medical Devices Segment Product Net Sales	$ 763.8	$ 837.4	$ 774.0
Medical Devices Segment Product Net Sales			
Domestic	60.5%	62.0%	65.1%
International	39.5%	38.0%	34.9%
Specialty Pharmaceuticals Segment Operating Income (2)	$ 1,370.8	$ 1,220.1	$ 1,047.9
Medical Devices Segment Operating Income (2)	189.2	222.0	207.1
Consolidated Long-Lived Assets			
Domestic	$ 3,673.2	$ 3,781.0	$ 3,702.8
International	577.4	553.8	557.5

(1) Other medical device product sales primarily consist of sales of ophthalmic surgical devices pursuant to a manufacturing and supply agreement entered into as part of the sale of the former Cornéal ophthalmic surgical device business in the third quarter of 2007, which was substantially concluded in the fourth quarter of 2007.

(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 business combinations and asset acquisitions 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.

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 18, 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.

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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 chronic dry eye, glaucoma, inflammation, infection and allergy.

Chronic Dry Eye. Restasis® (cyclosporine ophthalmic emulsion) 0.05%, or *Restasis®*, is the first, and currently the only, prescription therapy for the treatment of chronic dry eye worldwide. *Restasis®* is our best selling eye care product. Chronic dry eye is a painful and irritating condition involving abnormalities and deficiencies in the tear film initiated by a variety of causes. The incidence of chronic dry eye increases markedly with age, after menopause in women and in people with systemic diseases such as Sjögren s syndrome and rheumatoid arthritis. Until the approval of *Restasis®*, physicians used lubricating tears to provide palliative relief of the debilitating symptoms of chronic dry eye. We launched *Restasis®* in the United States in 2003 under a license from Novartis AG, or Novartis, for the ophthalmic use of cyclosporine. *Restasis®* is currently approved in 34 countries.

Artificial Tears. Our artificial tears products, including the *Refresh®* and *Refresh® Optive* brands, treat dry eye symptoms including irritation and dryness due to pollution, computer use, aging and other causes. *Refresh®*, launched in 1986, is the best selling over-the-counter artificial tears brand in the United States and includes a wide range of preserved and non-preserved drops as well as ointments to treat dry eye symptoms. According to IMS Health Incorporated, an independent marketing research firm, our artificial tears products, including the *Refresh®* and *Refresh® Optive* brands, were again the number one selling artificial tears products worldwide for the first nine months of 2009.

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 70 million people worldwide have glaucoma. According to IMS Health Incorporated, our products for the treatment of glaucoma, including *Lumigan®* (bimatoprost ophthalmic solution) 0.03%, or *Lumigan®* 0.03%, *Lumigan®* 0.01%, *Alphagan®* (brimonidine tartrate ophthalmic solution) 0.2%, or *Alphagan®*, *Alphagan® P* 0.15%, *Alphagan® P* 0.1%, *Combigan®* (brimonidine tartrate/timolol maleate ophthalmic solution) 0.2%/0.5%, or *Combigan®*, and *Ganfort* (bimatoprost/timolol maleate ophthalmic solution), or *Ganfort*, captured approximately 19% of worldwide glaucoma market sales for the first nine months of 2009.

Lumigan® 0.03% and *Lumigan®* 0.01% are topical treatments indicated for the reduction of elevated intraocular pressure in patients with glaucoma or ocular hypertension. *Lumigan®* 0.01% is an improved reformulation of *Lumigan®* 0.03% for sale in certain countries outside of the United States. We are also seeking approval of *Lumigan®* 0.01% in the United States. We currently sell *Lumigan®* 0.01% and *Lumigan®* 0.03% in over 75 countries worldwide and, together, they are our second best selling eye care products. According to IMS Health Incorporated, *Lumigan®* 0.01% and *Lumigan®* 0.03% were the fourth best selling glaucoma products in the world for the first nine months of 2009. In 2002, the European Commission approved *Lumigan®* 0.03%. In 2004, the European Union s Committee for Proprietary Medicinal Products approved *Lumigan®* 0.03% as a first-line therapy for the reduction of elevated intraocular pressure in chronic open-angle glaucoma and ocular hypertension. In 2006, the FDA approved *Lumigan®* 0.03% as a first-line therapy. In 2004, we entered into an exclusive licensing agreement with Senju Pharmaceutical Co., Ltd., or Senju, under which Senju became responsible for the development and commercialization of *Lumigan®* 0.03% in Japan. In the third quarter of 2009, Senju received approval of *Lumigan®* 0.03% in Japan. In the second quarter of 2009, Health Canada approved *Lumigan®* 0.01%. *Lumigan®* 0.01% was also approved in Brazil in 2009. In the first quarter of 2010, the European Commission granted a Marketing Authorization for *Lumigan®* 0.01% in the 27 European Union member states.

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In 2006, we received a license from the European Commission to market *Ganfort* in the European Union. Combined sales of *Lumigan*® 0.03%, *Lumigan*® 0.01% and *Ganfort* represented approximately 10% of our total consolidated product net sales in 2009, 2008 and 2007. *Ganfort* is now sold in over 29 countries outside the United States.

Our third best selling eye care products are the ophthalmic solutions *Alphagan*®, *Alphagan*® *P* 0.15% and *Alphagan*® *P* 0.1%. These products lower intraocular pressure by reducing aqueous humor production and increasing uveoscleral outflow. *Alphagan*® *P* 0.15% and *Alphagan*® *P* 0.1% are improved reformulations of *Alphagan*® containing brimonidine, the active ingredient in *Alphagan*®, preserved with *Purite*®. We currently market *Alphagan*®, *Alphagan*® *P* 0.15% and *Alphagan*® *P* 0.1% in over 70 countries worldwide.

Alphagan®, *Alphagan*® *P* 0.15% and *Alphagan*® *P* 0.1% combined were the fourth best selling glaucoma products in the world for the first nine months of 2009, according to IMS Health Incorporated. Combined sales of *Alphagan*®, *Alphagan*® *P* 0.15% and *Alphagan*® *P* 0.1% and *Combigan*® represented approximately 9% of our total consolidated product net sales in 2009, 2008 and 2007. In 2002, based on the acceptance of *Alphagan*® *P* 0.15%, we discontinued the U.S. distribution of *Alphagan*®. In 2004, we entered into an exclusive licensing agreement with Kyorin Pharmaceutical Co., Ltd., or Kyorin, under which Kyorin became responsible for the development and commercialization of *Alphagan*® and *Alphagan*® *P* 0.15% in Japan. Kyorin subsequently sublicensed its rights under the agreement to Senju. *Alphagan*® *P* 0.1% was launched in the United States in 2006. The marketing exclusivity period for *Alphagan*® *P* 0.1% expired in the third quarter of 2008, although we have a number of patents covering the *Alphagan*® *P* 0.1% and *Alphagan*® *P* 0.15% technology that extend to 2022 in the United States. In 2003, the FDA approved the first generic of *Alphagan*®. Additionally, a generic form of *Alphagan*® is sold in a limited number of other countries, including Canada, Mexico, India, Brazil, Colombia, Argentina and other countries in the European Union.

In addition to our *Alphagan*® and *Lumigan*® products, we developed the ophthalmic solution *Combigan*®, a brimonidine and timolol combination designed to treat glaucoma and ocular hypertension in people who are not responsive to treatment with only one medication and are considered appropriate candidates for combination therapy. In 2005, we received positive opinions for *Combigan*® from 20 concerned member states included in the *Combigan*® Mutual Recognition Procedure for the European Union, and we launched *Combigan*® in the European Union during 2006. In the fourth quarter of 2007, the FDA approved *Combigan*® and we launched *Combigan*® in the United States. *Combigan*® is now sold in over 55 countries worldwide.

Inflammation. Our leading ophthalmic anti-inflammatory product is *Acular LS*® (ketorolac ophthalmic solution) 0.4%, or *Acular LS*®. *Acular LS*® is a version of *Acular*® that has been reformulated for the reduction of ocular pain, burning and stinging following corneal refractive surgery. *Acular*® *PF* was the first 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 best selling ophthalmic NSAID in the world during the first nine months of 2009, according to IMS Health Incorporated. In the third quarter of 2009, the FDA approved *Acuvail*® (ketorolac tromethamine ophthalmic solution) 0.45%, or *Acuvail*®, an advanced unit-dose preservative-free formulation of ketorolac for the treatment of pain and inflammation following cataract surgery and we began marketing *Acuvail*®. In the fourth quarter of 2009, the FDA approved four Abbreviated New Drug Applications, or ANDAs, for ketorolac tromethamine ophthalmic solution 0.5%, a generic version of *Acular*®, and four companies launched generic versions of *Acular*® in the United States. Our ophthalmic anti-inflammatory product *Pred Forte*® remains a leading topical steroid worldwide based on 2009 sales. *Pred Forte*® has no patent protection or marketing exclusivity and faces generic competition.

Infection. Our leading anti-infective is *Zymar*® (gatifloxacin ophthalmic solution) 0.3%, or *Zymar*®, which we license from Kyorin and have worldwide ophthalmic commercial rights excluding Japan, Korea, Taiwan and certain other countries in Asia and Europe. We launched *Zymar*® in the United States in 2003. *Zymar*® is a fourth-generation fluoroquinolone for the treatment of bacterial conjunctivitis and is currently approved in 33 countries. Laboratory studies have shown that *Zymar*® kills the most common bacteria that cause eye infections

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as well as specific resistant bacteria. We completed our Phase 3 clinical studies of an enhanced formula of *Zymar*® for bacterial conjunctivitis and filed a New Drug Application, or NDA, with the FDA in the third quarter of 2009. According to Verispan, an independent research firm, *Zymar*® was the number two ophthalmic anti-infective prescribed by ophthalmologists in the United States in 2009. *Zymar*® was the third best selling ophthalmic anti-infective product in the world for the first nine months of 2009, according to IMS Health Incorporated.

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., a business unit of Sanofi-Aventis, and hold worldwide ophthalmic commercial rights excluding Japan. *Alocril*® is approved in the United States, Canada and Mexico. We license *Elestat*® from Boehringer Ingelheim AG, and hold worldwide ophthalmic commercial rights excluding Japan. *Elestat*® is used for the prevention of itching associated with allergic conjunctivitis. We co-promote *Elestat*® in the United States under an agreement with Inspire Pharmaceuticals, Inc., or Inspire, within the ophthalmic specialty area and to allergists. 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*® (together with sales under its brand names *Relestat*® and *Purivist*®) is currently approved in 47 countries and was the fifth best selling ophthalmic allergy product in the world (and fourth in the United States) for the first nine months of 2009, according to IMS Health Incorporated.

Retinal Disease. In the second quarter of 2009, the FDA approved *Ozurdex* (dexamethasone intravitreal implant) 0.7 mg, or *Ozurdex* , as the first drug therapy indicated for the treatment of macular edema following branch retinal vein occlusion or central retinal vein occlusion. *Ozurdex* is a novel bioerodable formulation of dexamethasone in Allergan s proprietary *Novadur* sustained-release drug delivery system that can be used to locally and directly administer medications to the retina. We launched *Ozurdex* in the United States in the third quarter of 2009.

Neuromodulator

Our neuromodulator product, *Botox*® (onabotulinumtoxinA), or *Botox*®, has a long-established safety profile and has been approved by the FDA for more than 20 years to treat a variety of medical conditions, as well as for aesthetic use since 2002. With more than 2,000 publications on *Botox*® and *Botox*® Cosmetic in scientific and medical journals, results of approximately 50 randomized, placebo-controlled, clinical trials involving more than 11,000 patients, *Botox*® is a widely researched medicine with more than 100 potential therapeutic and aesthetic uses reported in the medical literature. Nearly 17 million treatment sessions have been recorded with *Botox*® and *Botox*® Cosmetic in the United States alone over the past 15 years (1994-2008). Marketed as *Botox*®, *Botox*® Cosmetic, *Vistabel*® or *Vistabex*®, depending on the indication and country of approval, the product is currently approved in approximately 80 countries for up to 21 unique indications. In the second quarter of 2009, following the approval of *Dysport* in the United States, we adopted a Risk Evaluation and Mitigation Strategies program, or REMS, including a boxed warning about the potential spread of botulinum toxins from the site of injection and the lack of interchangeability among botulinum toxin products. Sales of *Botox*® represented approximately 29%, 30% and 31% of our total consolidated product net sales in 2009, 2008 and 2007, respectively. The decline in the percentage of our total net sales represented by sales of *Botox*® primarily resulted from the growth in our eyecare franchises and the significant increase in our total consolidated product net sales as a result of the Inamed acquisition. *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;

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cervical dystonia, or sustained contractions or spasms of muscles in the shoulders or neck in adults, along with associated neck 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, spasticity associated with pediatric cerebral palsy and upper limb spasticity in post-stroke patients. We are currently in development for *Botox*® in the United States and Europe for new indications, including chronic migraine, upper limb spasticity, lower limb spasticity, neurogenic overactive bladder, idiopathic overactive bladder and benign prostate hyperplasia. In 2005, we announced plans to conduct two Phase 3 clinical trials to investigate the safety and efficacy of *Botox*® as a prophylactic therapy in patients with chronic migraine. In the third quarter of 2008, we announced completion of a top-line analysis of our Phase 3 clinical trials, which found that *Botox*® treatment decreased the number of headache days patients with chronic migraines suffered compared to patients receiving placebo injections. In addition, *Botox*® treatments were well tolerated in the trials in patients suffering from chronic migraines and patients receiving *Botox*® scored statistically significantly higher improvement in quality of life compared to patients receiving placebo injections. Based on this data, we filed a supplemental Biologics License Application, or sBLA, with the FDA for the use of *Botox*® to treat chronic migraine in the third quarter of 2009 and submitted regulatory files in the fourth quarter of 2009 to the authorities in the United Kingdom, France, Switzerland and Canada. In the second quarter of 2009, we received a complete response letter from the FDA regarding our sBLA for use of *Botox*® to treat upper limb spasticity, and we submitted additional data requested by the FDA in its complete response letter in the third quarter of 2009. In 2005, we reached agreement with the FDA to enter Phase 3 clinical trials for the use of *Botox*® to treat neurogenic overactive bladder and Phase 2 clinical trials for the use of *Botox*® to treat idiopathic overactive bladder. We fully enrolled our Phase 3 clinical trials for the use of *Botox*® to treat neurogenic overactive bladder in 2009. We completed the Phase 2 clinical trials for the use of *Botox*® to treat idiopathic overactive bladder in 2008 and began enrolling patients in our Phase 3 clinical trials for the use of *Botox*® to treat idiopathic overactive bladder in 2009. In 2005, we initiated Phase 2 clinical trials outside the United States for the use of *Botox*® to treat benign prostate hyperplasia. In the second quarter of 2009, we filed an Investigational New Drug Application with the FDA relating to the use of *Botox*® to treat benign prostate hyperplasia.

Botox® *Cosmetic.* The FDA approved *Botox*® Cosmetic for the temporary improvement in the appearance of moderate to severe glabellar lines in adult men and women age 65 or younger in 2002. Referred to as *Botox*®, *Botox*® Cosmetic, *Vistabel*® or *Vistabex*®, depending on the country of approval, this product is administered in small injections to temporarily reduce the muscle activity that causes the formation of glabellar lines between the eyebrows that often develop during the aging process. Currently, more than 60 countries have approved facial aesthetic indications for *Botox*®, *Botox*® Cosmetic, *Vistabel*® or *Vistabex*®. In 2002, we launched comprehensive direct-to-consumer marketing campaigns, including television commercials, radio commercials, print advertising and interactive media aimed at dermatologists, plastic and reconstructive surgeons and other aesthetic specialty physicians, as well as consumers, in the United States. We also continue to sponsor aesthetic specialty physician training in approved countries to further expand the base of qualified physicians using *Botox*®, *Botox*® Cosmetic, *Vistabel*® or *Vistabex*®.

In 2005, we entered into a long-term arrangement with GlaxoSmithKline, or GSK, under which GSK agreed to develop and promote *Botox*® in Japan and China and we agreed to co-promote GSK s products *Imitrex STATdose System*® (sumatriptan succinate), or *Imitrex STATdose System*®, and *Amerge*® (naratriptan hydrochloride), or *Amerge*®, 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 we receive royalties on GSK s *Botox*® sales in Japan and China. We also manufacture *Botox*® for GSK as part of a long-term supply agreement and collaboratively support GSK in its new clinical developments for *Botox*® and its strategic marketing in those markets, for which we receive payments. In the first

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quarter of 2009, GSK received approval of *Botox*® in Japan for the treatment of glabellar lines and equinus foot due to lower limb spasticity in juvenile cerebral palsy patients and launched *Botox*® in Japan for these indications with the glabellar lines indication marketed as *Botox Vista*®. GSK also received approval of *Botox*® for the treatment of glabellar lines in China in the first quarter of 2009. In addition, we obtained the right to co-promote GSK s products *Imitrex STATdose System*® and *Amerge*® in the United States to neurologists for a 5-year period, for which we receive fixed and performance payments from GSK. *Imitrex STATdose System*® is approved for the treatment of acute migraine in adults and for the acute treatment of cluster headache episodes. *Amerge*® is approved for the acute treatment of migraine attacks with and without an aura in adults.

Skin Care Product Lines

Our skin care product lines focus on the acne, psoriasis, physician-dispensed skin care and eyelash growth markets, particularly in the United States and Canada.

Acne/Psoriasis

Aczone®. Our product *Aczone*® (dapsone) gel 5%, approved for sale in both the United States and Canada, is indicated for the treatment of acne vulgaris in patients 12 and older. *Aczone*® contains the first new FDA-approved chemical entity (dapsone) for acne treatment since *Tazorac*® (tazarotene) gel was approved in 1997. We launched *Aczone*® in the United States in the fourth quarter of 2008. In the third quarter of 2009, we entered into a co-promotion agreement with Quintiles under which Quintiles will co-promote *Aczone*®, targeting primary care physicians.

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

Tazarotene Products. We market *Tazorac*® (tazarotene) gel in the United States for the treatment of acne and plaque psoriasis, a chronic skin disease characterized by dry red patches. We also market a cream formulation of *Tazorac*® in the United States for the topical treatment of acne and for the treatment of psoriasis. We have also engaged Pierre Fabre Dermatologie as our promotion partner for *Zorac*® (tazarotene) in certain parts of Europe, the Middle East and Africa. In the third quarter of 2007, we entered into a strategic collaboration agreement with Stiefel Laboratories, Inc., which was acquired by GSK in 2009, to develop and market new products involving tazarotene for dermatological use worldwide.

Topical Aesthetic Skin Care

Avage®. Our product *Avage*® (tazarotene) cream is 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 2003.

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 in the United States.

Prevage® and *Prevage*® MD. In 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 2005, we entered into an exclusive license agreement with Elizabeth Arden, Inc., or Elizabeth Arden, granting Elizabeth Arden the right to globally market a new formulation of *Prevage*® containing 0.5% idebenone, to leading department stores and other prestige cosmetic retailers. In 2005, we began marketing *Prevage*® MD, containing 1% idebenone, to physicians in the United States.

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Vivité®. In the second quarter of 2007, we launched *Vivité®*, an advanced anti-aging skin care line that uses proprietary *GLX Technology*, creating a highly specialized blend of glycolic acid and natural antioxidants. We market our *Vivité®* line of skin care products to physicians in the United States.

Eyelash Growth

Latisse® (bimatoprost ophthalmic solution) 0.03%, or *Latisse®*, is the first, and currently the only, FDA-approved prescription treatment of eyelash hypotrichosis, or inadequate eyelashes. The FDA approved *Latisse®* in the fourth quarter of 2008 and we launched *Latisse®* in the United States in the first quarter of 2009. *Latisse®* is a once-daily prescription treatment applied to the base of the upper eyelashes with a sterile, single-use-per-eye disposable applicator. Patients using *Latisse®* typically experience noticeable eyelash growth in eight to 16 weeks. Continued treatment with *Latisse®* is required to maintain its effect. In the third quarter of 2009, *Latisse®* was approved by the Korea Food and Drug Administration. In the third quarter of 2009, we entered into a co-promotion agreement with Quintiles under which Quintiles will co-promote *Latisse®*, targeting primary care physicians.

Urologics

Sanctura® and *Sanctura XR®*. Following our acquisition of Esprit in the fourth quarter of 2007, we began marketing *Sanctura®*, a twice-a-day anticholinergic approved for the treatment of OAB. In the third quarter of 2007, the FDA approved *Sanctura XR®*, a once-daily anticholinergic for the treatment of OAB, and we launched *Sanctura XR®* in the first quarter of 2008. *Sanctura XR®* is well tolerated by patients and has demonstrated improvements in certain adverse side effects common in existing OAB treatments, including dry mouth. We obtained an exclusive license to market *Sanctura®* and *Sanctura XR®* in the United States and its territories from Indevus. We pay royalties to Indevus based upon our sales of *Sanctura®* and *Sanctura XR®* and assumed Esprit s obligations to pay certain other third-party royalties, also based upon sales of *Sanctura®* and *Sanctura XR®*. In the second quarter of 2008, we entered into a license agreement with Indevus and Madaus GmbH, which grants us the right to seek approval for and to commercialize *Sanctura XR®* in Canada. In the first quarter of 2010, Health Canada approved *Sanctura XR®*. In 2008, we announced plans to seek a partner to promote *Sanctura®* and *Sanctura XR®* to general practitioners in the United States, and in the first quarter of 2009, we announced a restructuring plan to focus our sales efforts on the urology specialty, which resulted in a significant reduction in our urology sales force. We substantially completed our restructuring and merged our medical dermatology and urology specialty sales forces into one combined sales force in 2009. In the third quarter of 2009, we entered into a co-promotion agreement with Quintiles under which Quintiles promotes *Sanctura XR®*, generally targeting primary care physicians. We continue to promote *Sanctura XR®* to the urology specialty channel using our existing sales force.

Medical Devices Segment

Breast Aesthetics

For more than 25 years, our silicone gel and saline breast implants, consisting of a variety of shapes, sizes and textures, have been available to women in more than 60 countries for breast augmentation, revision and reconstructive surgery. 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 *Natrelle®*, *Inspira*, *McGhan* and *CUI* and the trademarks *BioCell®* , *MicroCell*, *BioDimensional®* and *Inamed®*. We currently market over 1,000 breast implant product variations worldwide to meet our customers preferences and needs.

Saline Breast Implants. We sell saline breast implants in the United States and worldwide for use in breast augmentation, revision and reconstructive surgery. The U.S. market is the primary market for our saline breast implants. Following the approval of silicone gel breast implants by Health Canada in October 2006 and the FDA

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in November 2006, the U.S. and Canadian markets have been undergoing a transition from saline breast implants to silicone gel breast implants.

Silicone Gel Breast Implants. We sell silicone gel breast implants in the United States and worldwide for use in breast augmentation, revision and reconstructive surgery. The safety of our silicone gel breast implants is supported by our extensive preclinical device testing, their use in over one million women worldwide and 20 years of U.S. clinical experience involving more than 150,000 women. The FDA approved our silicone gel breast implants in November 2006 based on the FDA s review of interim data from our 10-year core clinical study and our preclinical studies, its review of studies by independent scientific bodies and the deliberations of advisory panels of outside experts. Following approval, we are required to comply with a number of conditions, including our distribution of labeling to physicians and the distribution of our patient planner, which includes our informed consent process to help patients fully consider the risks associated with breast implant surgery. In addition and pursuant to the conditions placed on the FDA s approval of our silicone gel breast implants, we continue to monitor patients in the 10-year core clinical study and the 5-year adjunct clinical study and, in the first quarter of 2007, we initiated the Breast Implant Follow-Up Study, or BIFS, a 10-year post-approval clinical study. The 10-year core clinical study, which we began in 1999 and had fully enrolled in 2000 with approximately 940 augmentation, revision or reconstructive surgery patients, was designed to establish the safety and effectiveness of our silicone gel breast implants. We plan to continue to monitor patients in the 10-year core clinical study through the end of the study. In November 2006, we terminated new enrollment into our 5-year adjunct study, which was designed to further support the safety and effectiveness of silicone gel breast implants and which includes over 80,000 revision or reconstructive surgery patients. We plan to continue to monitor patients in the 5-year adjunct study through the end of the study. Finally, pursuant to the conditions placed on the FDA s approval of our silicone gel breast implants, we initiated BIFS, a new 10-year post-approval study of approximately 40,000 augmentation, revision or reconstructive surgery patients with silicone gel implants and approximately 20,000 augmentation, revision or reconstructive surgery patients with saline implants acting as a control group. In the fourth quarter of 2008, the FDA approved a modification to BIFS, which reduced the number of patients with saline breast implants from 20,000 to approximately 15,000. BIFS is designed to provide data on a number of endpoints including, for example, long-term local complications, connective tissue disease issues, neurological disease issues, offspring issues, reproductive issues, lactation issues, cancer, suicide, mammography issues and to study magnetic resonance imaging compliance and rupture results.

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 folds. Our primary facial aesthetics products are the *Juvéderm*® dermal filler family of products, *Zyderm*® and *Zyplast*® and *CosmoDerm*® and *CosmoPlast*®.

Juvéderm®. Our *Juvéderm*® dermal filler family of products, including *Juvéderm*®, *Voluma*®, *Softline*®, *Hydrafill* and *Surgiderm*®, are developed using our proprietary *Hylacross* technology, a technologically advanced manufacturing process that results in a smooth consistency gel formulation. 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 hyaluronic acid dermal filler products. In 2006, the FDA approved *Juvéderm*® Ultra and Ultra Plus, indicated for wrinkle and fold correction, for sale in the United States. In Europe, we market various formulations of *Juvéderm*®, *Voluma*®, *Softline*®, *Hydrafill* and *Surgiderm*® for wrinkle and fold augmentation. The *Juvéderm*® dermal filler family of products are currently approved or registered in over 34 countries, including all major European markets.

In the second quarter of 2007, the FDA approved label extensions in the United States for *Juvéderm*® Ultra and Ultra Plus based on new clinical data demonstrating that the effects of both products may last for up to one

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year, which is a longer period of time than was reported in clinical studies that supported FDA approval of other hyaluronic acid dermal fillers. We began selling *Juvéderm*® Ultra 2, 3 and 4, containing lidocaine, an anesthetic that alleviates pain during injections, in Europe in the first quarter of 2008, and in Canada we began selling *Juvéderm*® Ultra and Ultra Plus with lidocaine in the fourth quarter of 2008. In 2008, we filed a Premarket Approval Supplement, or sPMA, with the FDA for *Juvéderm*® Ultra and Ultra Plus with lidocaine. The FDA approved our sPMA and we launched our lidocaine containing *Juvéderm*® Ultra XC and Ultra Plus XC in the first quarter of 2010.

Zyderm® and *Zyplast*®. *Zyderm*® and *Zyplast*® dermal fillers are injectable formulations of bovine collagen. The *Zyderm*® family of dermal fillers is formulated for people with fine line wrinkles or superficial facial contour defects. *Zyderm*® and *Zyplast*® dermal fillers 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. *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. *CosmoDerm*® and *CosmoPlast*® dermal fillers are formulated for people with fine line wrinkles or superficial facial contour defects. *CosmoDerm*® and *CosmoPlast*® implants do not require a skin test pre-treatment. Both of these products are formulated with lidocaine. *CosmoDerm*® and *CosmoPlast*® are approved for marketing in the United States, Canada and a number of European countries.

In the first quarter of 2007, our board of directors approved a plan to restructure and eventually sell or close the collagen manufacturing facility in Fremont, California that we acquired in the Inamed acquisition based on the anticipated reduction in market demand for human and bovine collagen products as a result of the introduction of our hyaluronic acid dermal filler products. Specifically, the plan involved a workforce reduction of approximately 59 positions, consisting principally of manufacturing positions at the facility, and lease termination and contract settlements. We began to record costs associated with the closure of the collagen manufacturing facility in the first quarter of 2007 and substantially completed all restructuring activities and closed the collagen manufacturing facility in the fourth quarter of 2008. Before closing the collagen manufacturing facility, we manufactured a sufficient quantity of collagen products to meet estimated market demand through 2010.

Obesity Intervention

We develop, manufacture and market several medical devices for the treatment of obesity. Our principal product in this 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 sleeve gastrectomy. The *Lap-Band*® System is an adjustable silicone band that is laparoscopically placed around the upper part of the stomach through a small incision, creating a small pouch at the top of the stomach. The new pouch fills faster, making the patient feel full sooner and, because the adjustable component of the band slows the passage of food, patients retain a feeling of fullness for longer periods of time. In addition to the anatomic effect of the pouch, data also suggests that patients with a properly adjusted band are less hungry due to neurological feedback to the brain.

The *Lap-Band*® System has achieved widespread acceptance in the United States and worldwide. In 2001, the FDA approved the *Lap-Band*® System to treat severe obesity in adults who have failed more conservative weight reduction alternatives. The *Lap-Band*® *VG*, a version of the *Lap-Band*® System with a larger band circumference, was approved by the FDA in 2004, and meets the needs of a wider range of patients. In the second quarter of 2007, we launched the *Lap-Band AP*® System, a next-generation of the *Lap-Band*® System. The *Lap-Band AP*® System has proprietary 360-degree *Omniform*® technology, which is designed to evenly distribute pressure throughout the band s adjustment range. The *Lap-Band AP*® also comes in two sizes, standard and large, to better serve patients who are physically larger, have thicker gastric walls or have substantial abdominal fat. Over 550,000 *Lap-Band*® System bands have been sold worldwide since 1993. In the first quarter

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of 2008, we completed enrollment in our pivotal adolescent study of *Lap-Band*® in patients aged 14 to 17 and submitted a sPMA to the FDA in the third quarter of 2009 seeking approval to market the *Lap-Band*® for the treatment of obesity in patients aged 14 to 17. Also in the first quarter of 2008, we completed enrollment of our lower body mass index, or BMI, pivotal study for *Lap-Band*® patients with a BMI of 30 to 40 and plan to review and submit data to the FDA in 2010.

In the fourth quarter of 2007, we entered into a co-promotion agreement with a subsidiary of Covidien Ltd., or Covidien, a leading global provider of health care products, under which Covidien co-promotes the *Lap-Band*® System to bariatric and other surgeons in the United States. Under the multi-year agreement, which became effective in the fourth quarter of 2007, Covidien utilizes its surgical devices sales force and other specialized staff, as an adjunct to our bariatric sales force and other specialized staff, to promote, educate and train surgeons on the *Lap-Band*® System. In the fourth quarter of 2009, we extended the co-promotion agreement with Covidien.

In the first quarter of 2007, we completed the acquisition of Swiss medical technology developer EndoArt SA, or EndoArt, a pioneer in the field of telemetrically-controlled (or remote-controlled) gastric bands used to treat morbid obesity and other conditions. We paid approximately $97.1 million, net of cash acquired, for all of the outstanding EndoArt shares. The EndoArt acquisition gave us ownership of EndoArt s proprietary technology platform, including *FloWatch*® technology, which powers the *EasyBand* Remote Adjustable Gastric Band System, or *EasyBand*, a next-generation, telemetrically-adjustable gastric banding device for the treatment of morbid obesity.

The *EasyBand*, like the *Lap-Band*® System, is implanted laparoscopically through a small incision. Clinical benefits of the *EasyBand* are similar to the *Lap-Band*® System s clinical benefits, except that adjustments to the *EasyBand* are done telemetrically rather than hydraulically, allowing for greater ease in adjustments and greater patient comfort.

We also sell the *Orbera* Intragastric Balloon System, which is a non-surgical alternative for the treatment of overweight and obese adults. Approved for sale in more than 60 countries but not in the United States, the *Orbera* 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 *Orbera* System is removed endoscopically within six months of placement, and is designed to be utilized in conjunction with a comprehensive diet and exercise program.

Other Products

Contigen®. *Contigen*® is our collagen product used for treatment of urinary incontinence due to intrinsic sphincter deficiency. C. R. Bard, Inc., or Bard, licenses from us the exclusive worldwide marketing and distribution rights to *Contigen*®. Prior to closing the Fremont manufacturing facility, we manufactured a sufficient supply of collagen to meet our contractual obligations to Bard through the expiration of our agreement with Bard in August 2011.

International Operations

Our international sales represented 34.6%, 35.4% and 34.3% of our total consolidated product net sales for the years ended December 31, 2009, 2008 and 2007, 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 sell our products directly and through independent distributors in over 100 countries worldwide. We maintain a global marketing team, as well as regional sales and marketing organizations, to support the

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promotion and sale of our products. We also engage contract sales organizations to promote certain products. Our sales efforts and promotional activities are primarily aimed at eye care professionals, neurologists, dermatologists, plastic and reconstructive surgeons, aesthetic specialty physicians, bariatric surgeons and urologists who use, prescribe and recommend our products. We advertise in professional journals, participate in medical meetings and utilize direct mail and Internet programs to provide descriptive product literature and scientific information to specialists in the ophthalmic, dermatological, medical aesthetics, bariatric, neurology, movement disorder and urology fields. We have developed training modules and seminars to update physicians regarding evolving technology in our products. In 2009, we also utilized direct-to-consumer advertising for our *Botox*® Cosmetic, *Juvéderm*®, the *Lap-Band*® System, *Latisse*® and *Restasis*® products.

Our products are sold to drug wholesalers, independent and chain drug stores, pharmacies, commercial optical chains, opticians, mass merchandisers, food stores, hospitals, group purchasing organizations, integrated direct hospital networks, ambulatory surgery centers and medical practitioners, including ophthalmologists, neurologists, dermatologists, plastic and reconstructive surgeons, aesthetic specialty physicians, bariatric surgeons, pediatricians, urologists and general practitioners. As of December 31, 2009, we employed approximately 2,650 sales representatives throughout the world. We also utilize distributors for our products in smaller international markets.

U.S. sales, including manufacturing operations, represented 65.4%, 64.6% and 65.7% of our total consolidated product net sales in 2009, 2008 and 2007, respectively. Sales to Cardinal Health, Inc. for the years ended December 31, 2009, 2008 and 2007 were 13.9%, 12.0% and 11.2%, respectively, of our total consolidated product net sales. Sales to McKesson Drug Company for the years ended December 31, 2009, 2008 and 2007 were 12.8%, 12.3% and 11.1%, respectively, of our total consolidated product net sales. No other country, or single customer, generated over 10% of our total consolidated product net sales.

We supplement our marketing efforts with exhibits 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 for using our products.

In the first quarter of 2009, we announced a restructuring plan that included a workforce reduction of approximately 460 employees, primarily from among our U.S. urology sales and marketing personnel as a result of our decision to focus on the urology specialty and to seek a partner to promote *Sanctura XR*® to general practitioners, and marketing personnel in the United States and Europe as we adjusted our back-office structures to a reduced short-term sales outlook for some of our businesses. We substantially completed our restructuring in 2009.

Research and Development

Our global research and development efforts currently focus on eye care, skin care, neuromodulators, medical aesthetics, obesity intervention, urology and neurology. 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, 2009, we had approximately 1,600 employees involved in our research and development efforts. Our research and development expenditures for 2009, 2008 and 2007 were approximately $706.0 million, $797.9 million and $718.1 million, respectively. Research and development expenditures in 2009 were less than 2008 and 2007. The decrease in research and development expenses primarily resulted from a reduction in spending on certain new technology discovery programs, the completion of several late-stage eye care pharmaceutical development programs, and a reduction in research and development expenses associated with in-licensing of in-process research and development technologies, partially offset by an increase in expenses

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for the development of certain medical devices and urology products. Excluding in-process research and development expenditures related to company acquisitions, we have increased our annual investment in research and development by over $363.1 million in the past five years.

Our strategy includes developing innovative products to address unmet medical needs and conditions associated with aging, and otherwise assisting patients in reaching life s potential. Our top priorities include furthering our leadership in ophthalmology, 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 chronic dry eye, pain and genitourinary diseases as well as next-generation breast implants, dermal fillers and obesity intervention devices. We plan to continue to build on our strong market positions in ophthalmic pharmaceuticals, medical aesthetics, medical dermatology, obesity intervention and neurology, and to explore new therapeutic areas that are consistent with our focus on specialty physician groups.

Our research and development efforts for the ophthalmic pharmaceuticals business focus primarily on new therapeutic products for retinal disease, glaucoma and chronic 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 eye diseases, including age-related macular degeneration and other retinal disorders. We concluded our Phase 3 studies for *Ozurdex* to treat macular edema following retinal vein occlusion, or RVO, utilizing our proprietary *Novadur* sustained-release drug delivery system that slowly releases dexamethasone, a potent steroid, to the back of the eye. In the second quarter of 2009, the FDA approved *Ozurdex* for the treatment of macular edema following RVO. In the fourth quarter of 2009, we filed a supplemental New Drug Application with the FDA for the approval of *Ozurdex* to treat non-infectious intermediate and posterior uveitis.

In 2005, we entered into an exclusive licensing agreement with Sanwa Kagaku Kenkyusho Co., Ltd., or Sanwa, to develop and commercialize *Ozurdex* for the ophthalmic specialty market in Japan. Under the terms of the agreement, Sanwa is responsible for the development and commercialization of *Ozurdex* in Japan and associated costs. Sanwa will pay us a royalty based on net sales of *Ozurdex* in Japan, makes clinical development and commercialization milestone payments and reimbursed us for certain expenses associated with our Phase 3 studies outside of Japan. We are working collaboratively with Sanwa on the clinical development of *Ozurdex*, as well as overall product strategy and management.

In the second quarter of 2008, the FDA approved *Trivaris*, a steroid with an anti-inflammatory action used for the treatment of retinal disease. Delivered via intravitreal injection, the ophthalmic indications for *Trivaris* include sympathetic ophthalmia, temporal arteritis, uveitis and ocular inflammatory conditions unresponsive to topical corticosteroids.

In the third quarter of 2009, we entered into a collaboration agreement with Pieris AG, or Pieris, a biopharmaceutical company engaged in the discovery and development of a novel class of targeted human proteins designed to diagnose and treat serious human disorders. The agreement combines Pieris proprietary technology with our expertise in drug delivery and ophthalmic drug development, with a goal of developing agents for the treatment of serious ocular disorders.

We continue to invest heavily in the research and development of neuromodulators, primarily *Botox*®and *Botox*® *Cosmetic*. We focus on both expanding the approved indications for *Botox*® and pursuing next-generation neuromodulator-based therapeutics. This includes expanding the approved uses for *Botox*® to include treatment for spasticity, chronic migraine, OAB and benign prostate hyperplasia. In collaboration with Syntaxin Ltd, 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 4 study of *Botox*® for the treatment of palmar hyperhidrosis, as part of our

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conditions of approval for axillary hyperhidrosis by the FDA. In addition, GSK received approval of *Botox*® in Japan for the treatment of glabellar lines and equinus foot due to lower limb spasticity in juvenile cerebral palsy patients and launched *Botox*® in Japan for these indications in the first quarter of 2009 with the glabellar lines indication marketed as *Botox Vista*®. GSK also received approval of *Botox*® in China for the treatment of glabellar lines during the first quarter of 2009.

We have a strategic research collaboration and license agreement with ExonHit Therapeutics, or ExonHit. The goals of this collaboration are to identify new molecular targets based on ExonHit s gene profiling *DATAS* technology and to work collaboratively to develop unique compounds and commercial products based on these targets. Our strategic alliance with ExonHit provides us with the rights to compounds developed in the fields of neurodegenerative disease, pain and ophthalmology. In 2007, we began development of a compound for a neurological indication as part of our collaboration with ExonHit. In the first quarter of 2009, we extended and expanded the scope of our collaboration with ExonHit.

In the fourth quarter of 2008, we entered into a strategic collaboration arrangement with Spectrum to develop and commercialize apaziquone, an antineoplastic agent currently being investigated for the treatment of non-muscle invasive bladder cancer. Under the collaboration, Spectrum is conducting two Phase 3 clinical trials to explore apaziquone s safety and efficacy as a potential treatment for non-muscle invasive bladder cancer following surgery. In the third quarter of 2009, the FDA granted Fast Track Designation for the investigation of apaziquone for the treatment of non-muscle invasive bladder cancer. Spectrum completed enrollment in the two Phase 3 clinical trials in the fourth quarter of 2009. Spectrum is conducting the apaziquone clinical trials pursuant to a joint development plan, and we bear the majority of these expenses. We will also make certain additional payments to Spectrum based on the achievement of certain development, regulatory and commercialization milestones and, following approval in countries outside of the United States and Asia, will make certain royalty payments on sales in such countries.

We also continue to invest in research and development around our *Juvéderm*® family of dermal filler products, including preparation for and ongoing clinical trials. In 2009, we filed a sPMA with the FDA for *Juvéderm*® Ultra and Ultra Plus with lidocaine, and in the first quarter of 2010, the FDA approved our lidocaine containing *Juvéderm*® Ultra XC and Ultra Plus XC.

In connection with our obesity intervention products, we are planning to conduct clinical trials of the *EasyBand* and have initiated a pivotal study of the *Orbera* System, with the goal of obtaining approval in the United States. In addition, in the first quarter of 2008, we completed enrollment in a pivotal adolescent study of *Lap-Band*® patients aged 14 to 17 and submitted a sPMA to the FDA in the third quarter of 2009 seeking approval to market the *Lap-Band*® for the treatment of obesity in patients aged 14 to 17. In the first quarter of 2008, we completed enrollment of our lower BMI pivotal study for *Lap-Band*® patients with a BMI of 30 to 40 and plan to review and submit data to the FDA in 2010.

The continuing introduction of new products supplied by our research and development efforts, including our clinical development projects, 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, clinical development 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 or clinical development 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 at the following locations: Westport, Ireland; San José, Costa Rica; Annecy, France; Waco, Texas; 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

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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, including *Sanctura*®, *Sanctura XR*® and *Aczone*® gel. For a discussion of the risks relating to the use of third party manufacturers, see Item 1A of Part I of this report, Risk Factors We could experience difficulties obtaining or creating the raw materials or components needed to produce our products and interruptions in the supply of raw materials or components could disrupt our manufacturing and cause our sales and profitability to decline.

In the first quarter of 2007, we announced the closing of the collagen manufacturing facility in Fremont, California that we acquired in the Inamed acquisition, and we substantially completed all restructuring activities and closed the facility in the fourth quarter of 2008. Before closing the facility, we manufactured a sufficient quantity of our collagen products to meet estimated market demand through 2010. In 2009, we closed our Arklow, Ireland breast implant manufacturing facility and transferred manufacturing to our San José, Costa Rica manufacturing plant.

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 program that identifies additional sources of key raw materials. In some cases, however, most notably with active pharmaceutical ingredients and silicone raw materials, we are a niche purchaser, 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 pharmaceutical and medical device products 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 foreign regulatory authorities to manufacture pharmaceuticals and 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, develop and market. 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

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principally compete on the basis of quality, product design, 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 Products. Our eye care pharmaceutical products, including *Acular®, Acular LS®*, *Acular® PF, Acuvail®, Alocril®, Alphagan®*, *Alphagan® P* 0.15%, *Alphagan® P* 0.1%, *Combigan®*, *Elestat®, Ganfort, Lumigan®* 0.03%, *Lumigan®* 0.01%, *Ozurdex*, *Pred Forte®, Refresh®*, *Restasis®* and *Zymar®*, face extensive competition from Alcon Laboratories, Inc., Bausch & Lomb Incorporated, Inspire Pharmaceuticals, Inc., Ista Pharmaceuticals, Inc., Merck & Co., Inc., Novartis AG, Pfizer Inc. and Santen Seiyaku. For our eye care products to be successful, we must be able to manufacture and effectively detail them to a sufficient number of eye care professionals such that they 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 is effective and well tolerated.

We also face competition from generic drug manufacturers in the United States and internationally. For instance, in 2009, the FDA approved four ANDAs for ketorolac tromethamine ophthalmic solution 0.5%, a generic version of *Acular®*, and four companies launched sales of generic versions of *Acular®* in the United States. In the fourth quarter of 2007, we received a paragraph 4 Hatch-Waxman Act certification from Apotex Corp. seeking FDA approval to market a generic form of *Zymar®*. In 2009, we received paragraph 4 Hatch-Waxman Act certifications from Sandoz, Inc., Hi-Tech Pharmacal Co., and Alcon Research, Ltd., seeking FDA approval of generic forms of *Combigan®*, Barr Laboratories, Inc. seeking FDA approval of a generic form of *Lumigan®* and Watson Pharmaceuticals, Inc. seeking FDA approval of a generic form of *Sanctura XR®*. See Item 3 of Part I of this report, Legal Proceedings and Note 14, Legal Proceedings, 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. *Botox®* was the only neuromodulator approved by the FDA until December 2000, when the FDA approved *Myobloc®* (rimabotulinumtoxinB), a neuromodulator formerly marketed by Elan Pharmaceuticals and now marketed by Solstice Neurosciences Inc. In the second quarter of 2009, the FDA approved *Dysport* (abobotulinumtoxinA) for the treatment of cervical dystonia and glabellar lines, which is marketed by Ipsen Ltd., or Ipsen, and Medicis Pharmaceutical Corporation, or Medicis, respectively. The approved package for *Dysport* included a boxed warning regarding the symptoms associated with the spread of botulinum toxin beyond the injection site. Additionally, the FDA approved Ipsen s and Medicis REMS program, which addresses the lack of interchangeability of botulinum toxin products and the risks associated with the spread of botulinum toxin beyond the injection site. Ipsen has marketed *Dysport* for therapeutic indications in Europe since 1991, prior to our European commercialization of *Botox®* in 1992. In 2006, Ipsen received marketing authorization for a cosmetic indication for *Dysport* in Germany. In 2007, Ipsen granted Galderma, a joint venture between Nestle and L Oréal Group, an exclusive development and marketing license for *Dysport* for cosmetic indications 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. In the first quarter of 2008, Galderma became Ipsen s sole distributor for *Dysport* in Brazil, Argentina and Paraguay. In the first quarter of 2009, the health authorities of 15 European Union countries approved *Dysport* for glabellar lines under the trade name *Azzalure*.

In addition, Merz Pharmaceuticals , or Merz s, botulinum toxin product *Xeomin®* is currently approved for therapeutic indications in Germany and many other countries in the European Union. In 2009, Merz received approval of *Bocouture®* (rebranded from *Xeomin®*) for glabellar lines in Germany, and recently filed *Bocouture®* for this indication in other European Union countries. *Xeomin®* is also approved for glabellar lines in Argentina and Mexico.

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Mentor Corporation, a division of Johnson & Johnson, or Mentor, is conducting clinical trials for a competing neuromodulator in the United States. A Korean botulinum toxin, *Meditoxin*®, was approved for sale in Korea in 2006. The company, Medy-Tox Inc., received exportation approval from Korean authorities in early 2005 to ship their product under the trade name *Neuronox*®, which is approved in Colombia for therapeutic and cosmetic indications under the trade name *SIAX* and is approved in Brazil for therapeutic indications under the name *Botulift*.

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. While these products are unlikely to meet stringent U.S. regulatory standards, the companies operating in these markets may be able to produce products at a lower cost than we can.

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.

Skin Care Product Line. Our skin care products, including *Aczone*®, *Azelex*®, *Tazorac*®, *Avage*®, *M.D. Forte*®, *Prevage*® MD, *Vivité*® and *Latisse*® focus on the acne, psoriasis, physician-dispensed skin care and eyelash growth markets, particularly in the United States and Canada, and compete with many other skin care products from companies, including among others, Dermik, a division of Sanofi-Aventis, Galderma, Medicis, Stiefel Laboratories, Inc., a division of GSK, Novartis, Merck & Co., Inc., Johnson & Johnson, Obagi Medical Products, Inc., L Oréal Group, SkinMedica, Inc. and Valeant Pharmaceuticals International, many of which have greater resources than us. We also compete with over-the-counter products that are designed to treat skin care issues similar to those for which our products are indicated. For example, *Aczone*® faces competition from several generic and over-the-counter products, which provide lower-priced options for the treatment of acne. We also face competition from generic skin care products in the United States and internationally.

Urologics. Our products for the treatment of OAB, *Sanctura*® and *Sanctura XR*®, compete with several other OAB treatment products, many of which have been on the market for a longer period of time, including Pfizer Inc. s *Detrol*®, *Detrol*® *LA* and *Toviaz*, Watson Pharmaceuticals, Inc. s *Oxytrol*® and *Gelnique*, Novartis Pharmaceuticals Corporation and the Procter & Gamble Company s *Enablex*® and Astellas Pharma US, Inc. and GSK s *Vesicare*® and certain generic OAB products. In the third quarter of 2009, we entered into a co-promotion agreement with Quintiles under which Quintiles will promote *Sanctura XR*® , targeting primary care physicians. We will continue to promote *Sanctura XR*® to the urology specialty channel using our existing sales force. We also face competition from generic urologic drug manufacturers in the United States and internationally. For our urologics products to be successful, we must be able to effectively detail our products to a sufficient number of urologists, obstetrician/gynecologists, primary care physicians and other medical specialists such that they recommend our products to their patients. We will also have to demonstrate that our products are safe and reduce patients sense of urgency, frequency and urge urinary incontinence episodes while also having limited side effects, such as dry mouth, constipation, blurred vision, drowsiness and headaches. We also have to demonstrate the effectiveness of our urologics products to Medicare and other governmental agencies to secure an appropriate and competitive level of reimbursement.

Medical Devices Segment

Breast Aesthetics. We compete in the U.S. breast implant market with Mentor. Mentor announced that, like us, it received FDA approval in November 2006 to sell its silicone breast implants in the United States. The

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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. In the United States, Sientra, Inc. is conducting clinical studies of saline breast implant products. Internationally, we compete with several manufacturers, including Mentor, Silimed, MediCor Ltd and its subsidiaries BioSil Ltd, Nagor and Eurosilicone, Poly Implant Prostheses, Sebbin Laboratories and certain Chinese implant manufacturers.

Obesity Intervention. Ethicon Endo-Surgery, Inc., a subsidiary of Johnson & Johnson, received FDA approval in the third quarter of 2007 to market its gastric band product, the *Realize* Personalized Banding Solution, or the *Realize* band, in the United States. The *Realize* band began competing with our *Lap-Band*® System in the United States in the fourth quarter of 2007. Outside the United States, the *Lap-Band*® System competes primarily with the *Realize* band and the *Heliogast*® Adjustable Gastric Ring (manufactured by Helioscopie, S.A., France, or Helioscopie). 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, sleeve gastrectomy 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 sells the *Heliosphere* intragastric balloon in competition with our *Orbera* products in certain countries in the European Union and Latin America.

Facial Aesthetics. Our facial products compete in the dermatology and plastic surgery markets with other hyaluronic acid products and animal- or cadaver-based collagen products as well as other polymer/bioceramic- based injectables, and indirectly with substantially different treatments, such as laser treatments, chemical peels, fat injections and botulinum toxin-based products. 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. In the United States, our dermal filler products, including *Juvéderm*® Ultra and Ultra Plus, compete with Medicis products *Restylane*® and *Perlane*, which were approved by the FDA in 2004 and the second quarter of 2007, respectively. In 2009, we filed a sPMA with the FDA for *Juvéderm*® Ultra and Ultra Plus with lidocaine, and in the first quarter of 2010, the FDA approved our lidocaine containing *Juvéderm*® Ultra XC and Ultra Plus XC. In the first quarter of 2010, the FDA also approved new formulations of *Restylane*® and *Perlane* containing lidocaine. In addition, we compete with *Radiesse*®, a bioceramic-based hydroxyl apatite dermal filler from BioForm Medical, Inc., which received FDA approval in 2006. In the first quarter of 2010, BioForm Medical, Inc. merged with Merz Pharma Group. Internationally, we compete with products such as *Restylane*®*, Restylane*® Fine Lines and *Perlane* (all manufactured by Q-Med A.B.) and a large number of other hyaluronic acid, bioceramic, protein and other polymer-based dermal fillers.

Government Regulation

Specialty Pharmaceuticals Segment

Drugs and biologics are subject to regulation by the FDA, state agencies and 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, regulations with respect to drugs and the Public Health Services Act and its implementing regulations 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 is long and expensive. We must complete preclinical laboratory and animal testing, submit an Investigational New Drug Application, which must become effective before United States clinical trials may begin, and perform 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

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overlap, and must satisfy extensive Good Clinical Practice regulations and informed consent regulations. Further, an independent institutional review board, or IRB, for each medical center or medical practice proposing to conduct the clinical trial must review and approve the plan for any clinical trial before it commences at that center or practice 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. In addition, the Food and Drug Administration Amendments Act of 2007, or FDAAA, imposes certain clinical trial registry obligations on study sponsors, including the posting of detailed trial design and trial results in the FDA public databases.

We must submit an NDA for a new drug, or a Biologics License Application, or BLA, for a biologic to the FDA, and the NDA or BLA must be reviewed and approved by the FDA before the drug or 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 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 FDA s current cGMPs 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 require post-marketing clinical studies, known as Phase 4 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. 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.

The manufacture and distribution of drugs and biologics are subject to continuing regulation by the FDA, including recordkeeping requirements, reporting of adverse experiences associated with the drug, and cGMPs, which regulate all aspects of the manufacturing process and impose certain procedural and documentation requirements. Drug and biologic manufacturers and their subcontractors are required to register their establishments, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with regulation requirements. Further, the FDAAA, which went into law in 2007, provided the FDA with additional authority over post-market safety. The FDAAA permits the FDA to require sponsors to conduct post-approval clinical studies, to mandate labeling changes based on new safety information and to require sponsors to implement a REMS program. The FDA may require a sponsor to submit a REMS program before a product is approved, or after approval based on new safety information. A REMS program may include a medication guide, a patient package insert, a plan for communicating risks to health care providers or other elements that the FDA deems necessary to assure the safe use of the drug. If the manufacturer or distributor fails to comply with the statutory and regulatory requirements, or if safety concerns arise, the FDA may take legal or regulatory action, including civil or criminal penalties, suspension, withdrawal or delay in the issuance of approvals, or seizure or recall of products, 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 including Internet marketing. Drugs and biologics can only be marketed for approved indications and in accordance with the labeling approved by the FDA. Failure to comply with these regulations can result in penalties, including the issuance of warning letters directing a company to correct deviations from FDA standards, a requirement that future advertising and promotional materials be pre-cleared by the FDA, and federal and state civil and criminal investigations and prosecutions. The FDA does not, however, regulate the behavior of physicians in their practice of medicine and choice of treatment. Physicians may prescribe (although

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manufacturers 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.

We are also subject to various laws and regulations regarding laboratory practices, the housing, care and 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 our operations and issue 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 are intended to improve the efficiency of operation of both the mutual recognition and centralized procedures to license medicines. Similar rules and regulations exist in countries around the world. 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. Legislation passed in recent years has imposed certain changes to the way in which pharmaceuticals, including our products, are covered and reimbursed in the United States. For instance, federal legislation and regulations have created a voluntary prescription drug benefit, Medicare Part D, and have imposed significant revisions to the Medicaid Drug Rebate Program. These changes have resulted in, and may continue to result in, coverage and reimbursement restrictions and increased rebate obligations. In addition, there is growing political pressure to allow the importation of pharmaceutical and medical device products from outside the United States. These reimbursement restrictions or other price reductions or controls or imports of pharmaceutical or medical device products from outside of the United States 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. Initiatives in these areas could subject Medicare and Medicaid reimbursement rates to change at any time. We 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.

Medical Devices Segment

Medical devices are subject to regulation by the FDA, state agencies and 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. Our medical device

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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 submissions for 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, use or their withdrawal from the market.

Our medical device products 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, or PMA, application in accordance with the FFDCA and its implementing regulations. 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 may require the manufacturer to submit to the FDA a premarket notification under Section 510(k) of the FFDCA requesting permission for commercial distribution. 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 had 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 after submission of the notification, although clearance can take significantly longer. If a device receives 510(k) clearance, any modification that could significantly affect its safety or efficacy, or that would constitute a major change in its intended use, design or manufacture requires a new 510(k) clearance or 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 is safe and effective for its intended use. The FDA, by statute and regulation, has 180 days to review and accept a PMA application, although the review generally occurs over a significantly longer period of time, and can take up to several years. The FDA may also convene an advisory panel of experts outside the FDA to review and evaluate the PMA 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 require information to support the changes and may include clinical data.

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, which 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, as well as approval by the FDA and the IRB overseeing the trial. In addition, the FDAAA imposes certain clinical trial

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registry obligations on study sponsors. 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:

- establishing registration and device listings with the FDA;
- Quality System Regulation, or QSR, 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;
- medical device reporting 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; and
- corrections and removal reporting regulations, which require that manufacturers report to the FDA field corrections and product recalls or removals if undertaken to reduce a risk to health posed by the device or to remedy a violation of the FFDCA that may present a health risk.

The FDA imposes a number of complex regulatory requirements on entities that advertise and promote medical devices, 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 including Internet marketing. Medical devices can only be marketed for indications approved or cleared by the FDA. Failure to comply with these regulations can result in penalties, the issuance of warning letters directing a company to correct deviations from FDA standards, a requirement that future advertising and promotional materials be pre-cleared by the FDA, and federal and state civil and criminal investigations and prosecutions. The FDA does not, however, regulate physicians in their practice of medicine and choice of treatment. Physicians may prescribe (although manufacturers are not permitted to promote) legally available devices for uses that are not described in the product s labeling and that differ from those tested by us and approved or cleared by the FDA. Such off-label uses are common across medical specialties.

A Class III device may have significant additional obligations imposed in its conditions of approval. 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 or other third party manufacturers. 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.

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Medical devices are also 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. Governments may delay reimbursement decisions after a device has been approved by the appropriate regulatory agency, impose rebate obligations or restrict patient access. In the United States, the federal government has proposed levying significant excise taxes on manufacturers based on their medical device sales. We cannot assure you that such taxes will not be levied on medical devices in the future or that such taxes would not have a material adverse effect on our results or operations.

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 are subject to federal and state laws pertaining to the privacy and security of personal health information, including but not limited to the Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (collectively, HIPAA). HIPAA mandates, among other things, the adoption of uniform standards for the electronic exchange of information in common health care transactions (e.g., health care claims information and plan eligibility, referral certification and authorization, claims status, plan enrollment, coordination of benefits and related information), as well as standards relating to the privacy and security of individually identifiable health information, which require the adoption of administrative, physical and technical safeguards to protect such information. In addition, many states have enacted comparable laws addressing the privacy and security of health information, some of which are more stringent then HIPAA.

We are also subject to various federal and state laws pertaining to health care fraud and abuse and gifts to health care practitioners. For example, 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. In addition, under California law, pharmaceutical companies must adopt a comprehensive compliance program that is in accordance with both the April 2003 Office of Inspector General Compliance Program Guidance for Pharmaceutical Manufacturers, or OIG Guidance, and the Pharmaceutical Research and Manufacturers of America Code on Interactions with Healthcare Professionals, or the PhRMA Code. The PhRMA Code seeks to promote transparency in relationships between health care professionals and the pharmaceutical industry and to ensure that pharmaceutical marketing activities comport with the highest ethical standards. The PhRMA Code contains strict limitations on certain interactions between health care professionals and the pharmaceutical industry relating to gifts, meals, entertainment and speaker programs, among others. Similarly, the Advanced Medical Technology Association s Revised Code of Ethics, or the AdvaMed Code, also seeks to ensure that medical device companies and health care professionals have collaborative relationships that meet high ethical standards, that medical decisions are based on the best interests of patients, and that medical device companies and health care professionals comply with applicable laws, regulations and government

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guidance. To that end, the AdvaMed Code provides guidance regarding how medical device companies may comply with certain aspects of the anti-kickback laws and OIG Guidance by outlining ethical standards for interactions with health care professionals. Furthermore, the federal False Claims Act prohibits anyone from, among other things, 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. HIPAA prohibits executing a scheme to defraud any health care 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 and other 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). In addition, certain states, such as Massachusetts and Minnesota, have imposed restrictions on the types of interactions that pharmaceutical and medical device companies or their agents (e.g. sales representatives) may have with health care professionals, including bans or strict limitations on the provision of meals, entertainment, hospitality, travel and lodging expenses, and other financial support, including funding for continuing medical education activities.

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*®, *Alphagan*® *P* 0.15%, *Alphagan*® *P* 0.1%, *Combigan*® and the U.S. patents relating to *Restasis*®, *Acular LS*®, *Zymar*®, *Acuvail*® and *Latisse*®, no one patent or license is materially important to our specialty pharmaceuticals segment. The U.S. patents covering *Lumigan*® expire in 2012 and 2014. The European patent covering *Lumigan*® expires in various countries between 2013 and 2017. The U.S. patent covering the commercial formulation of *Acular*® expired in the fourth quarter of 2009. The marketing exclusivity period for *Acuvail*® expires in the United States in 2012. The U.S. patents covering the commercial formulations of *Alphagan*® *P* 0.15%, and *Alphagan*® *P* 0.1% expire in 2012 and 2022. The U.S. patents covering *Restasis*® expire in 2014. The U.S. patents covering *Zymar*® expire in 2010, 2016 and 2020. The U.S. patents for *Combigan*® expire in 2022 and 2023. The marketing exclusivity period for *Combigan*® in the United States expires in the fourth quarter of 2010 and in Europe in 2015. The U.S. patents covering *Latisse*® expire in 2012, 2018, 2022 and 2024 and the European patents expire in 2013, 2018 and 2021. The marketing exclusivity period for *Latisse*® expires in the fourth quarter of 2011.

We have rights in well over 100 issued *Botox*® related U.S. and European use and process patents covering, for example, pain associated with cervical dystonia, treatment of chronic migraine, hyperhidrosis, OAB and benign prostate hyperplasia. We have granted royalty-bearing patent licenses to Merz with regard to *Xeomin*® in many countries where we have issued or pending patents and to Solstice Neurosciences with regard to *MyoBloc*®.

With the exception of certain U.S. and European patents relating to the *Lap-Band*® System and our *Inspira*® and *Natrelle*® Collection of breast implants, no one patent or license is materially important to our specialty medical device segment based on overall sales. The patents covering our *Lap-Band*® System, some of which we license from third parties, expire in 2011 and 2014 in the United States and in 2014 in Europe. The patents covering our *Inspira*® and *Natrelle*® Collection of breast implants expire in 2018 in the United States and in 2017 in Europe.

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

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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 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, require us to incur significant legal expenses and can preclude or delay the commercialization of products. See Item 3 of Part I of this report, Legal Proceedings and Note 14, Legal Proceedings, 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 and we regularly prosecute third party infringers of our trademarks in an attempt to limit confusion in the marketplace. 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 infringing those marks. 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 entered into an exclusive licensing agreement with Kyorin under which Kyorin became responsible for the development and commercialization of *Alphagan*® and *Alphagan*® *P* 0.15% in Japan. Kyorin subsequently sublicensed its rights under the agreement to Senju. 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 entered into an exclusive licensing agreement with Senju under which Senju became responsible for the development and commercialization of *Lumigan*® in Japan. Senju incurs associated costs,

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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. In the third quarter of 2009, Senju received approval of *Lumigan*® 0.03% in Japan.

We 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 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 licensed to GSK all clinical development and commercial rights to *Botox*® in Japan and China. We receive 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 in its new clinical developments for *Botox*® and its strategic marketing in those markets, for which we receive payments. In the first quarter of 2009, GSK received approval of *Botox*® in Japan for the treatment of glabellar lines and equinus foot due to lower limb spasticity in juvenile cerebral palsy patients and launched *Botox*® in Japan for these indications with the glabellar lines indication marketed as *Botox Vista*®. GSK also received approval of *Botox*® in China for the treatment of glabellar lines and launched *Botox*® in China in the first quarter of 2009.

As a result of the Esprit acquisition, we obtained an exclusive license to market *Sanctura*® and *Sanctura XR*® in the United States and its territories from Indevus. We pay royalties to Indevus based upon our sales of *Sanctura*® and *Sanctura XR*® and assumed obligations of Esprit to pay certain other third-party royalties, also based upon sales of *Sanctura*® and *Sanctura XR*®. In the second quarter of 2008, we entered into a license agreement with Indevus and Madaus GmbH, which grants us the right to seek approval for and to commercialize *Sanctura XR*® in Canada. In the first quarter of 2010, Health Canada approved *Sanctura XR*®.

We entered into a strategic collaboration arrangement with Spectrum to develop and commercialize apaziquone, an antineoplastic agent currently being investigated for the treatment of non-muscle invasive bladder cancer by intravesical instillation. Under the collaboration, Spectrum is conducting two Phase 3 clinical trials to explore apaziquone s safety and efficacy as a potential treatment for non-muscle invasive bladder cancer following surgery. In the third quarter of 2009, the FDA granted Fast Track Designation for the investigation of apaziquone for the treatment of non-muscle invasive bladder cancer. Spectrum completed enrollment in the two Phase 3 clinical trials in the fourth quarter of 2009. Spectrum retained exclusive rights to apaziquone in Asia, including Japan and China. We received exclusive rights to apaziquone for the treatment of bladder cancer in the rest of the world, including the United States, Canada and Europe.

In 2004, through our acquisition of Inamed, 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 and will pay royalties until the expiry of the applicable patents.

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.

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. We also pride ourselves on our comprehensive and successful environmental, health and safety programs and performance against internal objectives. We have been recognized many times for superior environmental health and safety performance.

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Although we continue to make capital expenditures for environmental protection, we do not anticipate any 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 a 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 aesthetic 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, restrict access or significantly influence the purchase of medical products and services. The market for some of 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 third-party payors, and consequently 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. For example, 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 who have previously been unsuccessfully treated for obesity and who have a BMI equal to or greater than 40 or a BMI of 35 when at least one co-morbidity is present. However, the policy reiterates that treatments for obesity alone are not covered, because such treatments are not considered reasonable and necessary. Without changing current coverage for morbidly obese individuals, effective February 12, 2009, the Centers for Medicare & Medicaid Services, or CMS, the agency responsible for implementing the Medicare program, determined that Type 2 diabetes mellitus is a co-morbid condition related to obesity under the existing policies. 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 governmental agencies, insurance carriers and employers 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

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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 health care 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 national budget for the type of product.

In the United States, there have been and continue to be a number of legislative initiatives to contain health care coverage and reimbursement by governmental and other payors. For example, effective January 1, 2006, 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 in the past that the federal government should 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 local governmental payors for medical devices and the procedures in which medical devices are used. In addition, the American Recovery and Reinvestment Act of 2009, also known as the stimulus package, includes $1.1 billion in funding to study the comparative effectiveness of health care treatments and strategies. This funding will be used, among other things, to conduct, support or synthesize research that compares and evaluates the risk and benefits, clinical outcomes, effectiveness and appropriateness of products. Congress has indicated that this funding is intended to improve the quality of health care, but it remains unclear how the research will impact coverage, reimbursement or other third-party payor policies.

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 our various breast implant 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, contralateral implant product replacement and some financial assistance for surgical procedures required within ten years of implantation. Breast implants sold and implanted outside of the United States 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, 2009, we employed approximately 8,300 persons throughout the world, including approximately 4,300 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.

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Executive Officers

Our executive officers and their ages as of February 26, 2010 are as follows:

Name	Age	Principal Positions with Allergan
David E.I. Pyott	56	Chairman of the Board and Chief Executive Officer (Principal Executive Officer)
F. Michael Ball	54	President, Allergan
James F. Barlow	51	Senior Vice President, Corporate Controller (Principal Accounting Officer)
Raymond H. Diradoorian	52	Executive Vice President, Global Technical Operations
Dianne Dyer-Bruggeman	60	Executive Vice President, Human Resources
Jeffrey L. Edwards	49	Executive Vice President, Finance and Business Development, Chief Financial Officer (Principal Financial Officer)
Douglas S. Ingram, Esq.	47	Executive Vice President, Chief Administrative Officer and Secretary
Scott M. Whitcup, M.D.	50	Executive Vice President, Research & Development, Chief Scientific Officer

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, and Edwards Lifesciences Corporation, a publicly-traded company focused on products and technologies to treat advanced cardiovascular diseases. Mr. Pyott is a member of the Directors Board of The Paul Merage School of Business at the University of California, Irvine (UCI). Mr. Pyott serves on the board of directors and the Executive Committee of the California Healthcare Institute, and serves on the board of directors, Executive Committee and as Chairman of the International Affairs Committee 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, and as a member of the Advisory Board for the Foundation of The American Academy of Ophthalmology. Mr. Pyott also serves on the Board of Trustees of Chapman University.

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 STEC, Inc., a publicly-traded manufacturer and marketer of computer memory and hard drive storage solutions.

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

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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.

Ms. Dyer-Bruggeman has served as Executive Vice President, Human Resources since joining Allergan in December 2008. Prior to joining Allergan, Ms. Dyer-Bruggeman served as Senior Vice President, Global Human Resources for Broadcom Corporation, a global technology company, from April 2004 through November 2008. From June 1995 to April 2004, Ms. Dyer-Bruggeman served as Vice President, Human Resources for Titan Corporation, a leading provider of information and communications products for the defense and homeland security industries.

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 and Secretary, as well as our Chief Ethics Officer, since October 2006. Mr. Ingram also served as General Counsel from January 2001 to June 2009, and from October 2003 through October 2006, Mr. Ingram served as Executive Vice President, General Counsel and Secretary, as well as our Chief Ethics Officer. 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 to that 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 LLP. Mr. Ingram manages the Global Legal Affairs, Global Regulatory Affairs, Compliance and Internal Audit, Corporate Communications, Global Trade Compliance, and the Information Technology organizations. 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, and Chief Scientific Officer since April 2009. Prior to that, Dr. Whitcup was 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, Inc., a publicly-traded pharmaceutical company.

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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. To be successful in these industries, we must be able to, among other things, effectively discover, develop, test and obtain regulatory approvals for products, 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.

Developments by our competitors, the entry of new competitors into the markets in which we compete, or consolidation in the pharmaceutical and medical device industries could make our products or technologies less competitive or obsolete. Our future growth depends, in part, on our ability to develop and introduce products which are more effective than those developed by our competitors. Sales of our existing products may decline rapidly if a new product is introduced that represents a substantial improvement over our existing products. Certain of our pharmaceutical products also compete with over-the-counter products which may be priced and regulated differently than our prescription products, and are subject to the evolving preferences of consumers.

We also face competition from lower-cost generic drug products. The patent rights that protect our products are of varying strength and duration, and the loss of patent protection is typically followed by generic substitutes. As a result, we may compete against generic products that are as safe and effective as our products, but sold at substantially lower prices. Generic competition may significantly reduce the demand for our products with which any such generic products compete.

Adverse U.S. and international economic conditions may reduce consumer demand for our products, causing our sales and profitability to suffer.

Adverse conditions in the U.S. and international economies and financial markets may continue to negatively affect our revenues and operating results. Many of our products, including *Refresh*®, *Botox*® Cosmetic, *Juvéderm*®, *Latisse*®, to a large extent the *Natrelle*® line of breast implants, and to a lesser extent the *Lap-Band*® System, have limited reimbursement or are not reimbursable by governmental or other health care plans and instead are partially or wholly paid for directly by the consumer. Adverse economic conditions impacting consumers, including among others, increased taxation, higher unemployment, lower consumer confidence in the economy, higher consumer debt levels, lower availability of consumer credit, higher interest rates and hardships relating to declines in the housing and stock markets, historically have caused consumers to reassess their spending choices and reduce their purchases of certain of our products. Any failure to attain our projected revenues and operating results as a result of reduced consumer demand due to adverse economic or market conditions could have a material adverse effect on our business, cause our sales and profitability to suffer, reduce our operating cash flow and result in a decline in the price of our common stock. Adverse economic and market conditions could also have a negative impact on our business by negatively affecting the parties with whom we do business, including among others, our business partners, creditors, third-party contractors and suppliers, causing them to fail to meet their obligations to us.

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We could experience difficulties obtaining or creating the raw materials or components needed to produce our products and interruptions in the supply of raw materials or components 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 cGMPs. We also obtain *Aczone®*, *Sanctura®* and *Sanctura XR®* under manufacturing agreements with sole source suppliers. If we experience difficulties acquiring sufficient quantities of these materials or products 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 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 the FDA s 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 decrease in our revenues. Additionally, certain of the manufacturing processes that we perform are only performed at one location worldwide. Furthermore, as a result of the credit crisis and current economic conditions, and while we analyze the financial solvency of our key suppliers, we cannot guarantee that our key suppliers will remain solvent or that we will be able to obtain sufficient supplies of key materials, particularly as we often represent a small part of the overall output of these manufacturers.

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 or label extensions 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 or clearance 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;

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the FDA may not approve our manufacturing processes or facilities;

the FDA may not approve our REMS program;

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 or label extensions 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 delays or unanticipated costs. For example, in May 2009, we received a complete response letter from the FDA regarding our sBLA for *Botox®* to treat upper limb spasticity in post-stroke adults. The complete response letter identified items needed to complete the sBLA submission, including that we independently verify underlying patient source documentation at study sites relating to one of the pivotal clinical studies conducted in 1999 and upon completion of the verification, provide the FDA an updated analysis**.** We submitted the additional data requested by the FDA in their complete response letter in the third quarter of 2009. Further, the FDA may require us to implement a REMS program to manage known or potential serious risks associated with our pharmaceutical products to ensure that the benefits of our products outweigh their risks. A REMS program can include patient package inserts, medication guides, communication plans, an implementation system and other elements necessary to assure safe use of our pharmaceutical product. If the FDA determines that a REMS program is necessary, the agency will not approve our product without an approved REMS program, which could delay approval or impose additional requirements on our products. In addition, we may be subject to enforcement actions, including civil money penalties if we do not comply with REMS program requirements. 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. Our facilities, our suppliers facilities and other third parties facilities on which we rely must pass pre-approval reviews and plant inspections and demonstrate 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, or continued market acceptance of, products such as *Aczone®, Alphagan® P* 0.15%, *Alphagan® P* 0.1%, *Botox®*, *Botox®* Cosmetic, *Combigan®*, *Elestat®*, *Ganfort*, *Juvéderm®*, the *Lap-Band®* System, *Latisse®*, *Lumigan®*, *Refresh®*, *Restasis®*, *Sanctura®*, *Sanctura XR®*, *Tazorac®, Vistabel®* and *Zymar®*, as well as the *Natrelle®* line of breast implant products, new indications for *Botox®*, and new products such as *Acuvail®*, and *Ozurdex* . We cannot assure you that our currently marketed products will not be subject to further regulatory review and action.

In February 2008, the FDA announced in an Early Communication its review of certain adverse events following the use of botulinum toxins, including *Botox®* and *Botox®* Cosmetic. In April 2009, simultaneously with its approval of *Dysport* , the FDA announced the completion of its review and has requested that we adopt a REMS program equivalent to the REMS program required for *Dysport* . In July 2009, the FDA approved our REMS program for *Botox®*, which addresses the risks related to botulinum toxin spread beyond the injection site and the lack of botulinum toxin interchangeability. Further, we cannot assure you that 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 or our direct-to-consumer advertising materials fail to be approved by the FDA, our operating results could be materially adversely affected.

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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 sell or license these rights to us 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 or manufacture similar products or devices at lower cost, without having had to incur significant research and development costs in formulating the product or designing the device. 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.

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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 also 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 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.

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 14, Legal Proceedings, 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 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

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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 and Border Protection, 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, or MMA. The MMA 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. For example, versions of the House and Senate bills introduced in 2009 to reform the health care industry in the United States included provisions that would have allowed the importation of pharmaceuticals from Canada and other countries. Although the provisions were not included in the final legislation passed by each chamber, we believe there will likely be future efforts to reintroduce similar proposals. Even if such changes to the U.S. import laws 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 and Border Protection and other government agencies. For example, Public Law Number 111-83, which was signed into law in October 2009 and provides appropriations for the Department of Homeland Security for the 2010 fiscal year, expressly prohibits the U.S. Customs and Border Protection 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 FFDCA. In addition, certain state and local governments have implemented importation schemes for their citizens and, in the absence of federal action to curtail such activities, other states and local governments may also 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 ownership of real property and the operation of our business will continue to expose us to risks of environmental liabilities.

Under various U.S. federal, state and local environmental laws, ordinances and regulations, a current or previous owner or operator of real property may be liable for the cost of removal or remediation of hazardous or toxic substances on, under or in such property. Such laws often impose liability whether or not the owner or operator knew of, or was responsible for, the presence of such hazardous or toxic substances. Environmental laws also may impose restrictions on the manner in which property may be used or the businesses that may be operated, and these restrictions may require expenditures. Environmental laws provide for sanctions in the event of noncompliance and may be enforced by governmental agencies or, in certain circumstances, by private parties. In connection with the acquisition and ownership of our properties, we may be potentially liable for such costs. The cost of defending against claims of liability, complying with environmental regulatory requirements or remediating any contaminated property could have a material adverse effect on our business, assets or results of operations. Any costs or expenses relating to environmental matters may not be covered by insurance.

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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.

A disruption at certain of our manufacturing sites would significantly interrupt our production capabilities, which could result in significant product delays and adversely affect our results.

Certain of our products are produced at single manufacturing facilities, including *Restasis*®, our breast implant products, our obesity intervention products and our dermal filler products. In addition, we manufacture *Botox*® at two structurally separate facilities located adjacent to one another at a single site. We face risks inherent in manufacturing our products at a single facility or at a single site. These risks include the possibility that our manufacturing processes could be partially or completely disrupted by a fire, natural disaster, terrorist attack, foreign governmental action or military action. In the case of a disruption, we may need to establish alternative manufacturing sources for these products. This would likely lead to substantial production delays as we build or locate replacement facilities and seek and obtain the necessary regulatory approvals. If this occurs, and our finished goods inventories are insufficient to meet demand, we may be unable to satisfy customer orders on a timely basis, if at all. Further, our business interruption insurance may not adequately compensate us for any losses that may occur and we would have to bear the additional cost of any disruption. For these reasons, a significant disruptive event at certain of our manufacturing facilities or sites could materially and adversely affect 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.

As part of the Inamed acquisition, we 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 has been and continues to be the subject of a significant number of product liability claims due to allegations that the medical devices cause disease or result in complications and other health conditions due to rupture, deflation or other product failure. 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 even if there has been explantation of the core device without replacement;
- patients in the core study receive magnetic resonance imaging tests, or MRIs, at seven and nine years;
- we conduct a large, 10-year post-approval study;