ALLERGAN INC Form 10-K March 01, 2011 Table of Contents

# **UNITED STATES**

# SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

# **FORM 10-K**

(Mark One)

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

For the Fiscal Year Ended December 31, 2010

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** (State or Other Jurisdiction of 95-1622442 (I.R.S. Employer Identification No.)

Incorporation or Organization)

2525 Dupont Drive

Irvine, California (Address of Principal Executive Offices)

(714) 246-4500

(Registrant s Telephone Number, Including Area Code)

92612

(Zip Code)

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### Edgar Filing: ALLERGAN INC - Form 10-K

#### 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 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 b 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 b

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  $\flat$  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 b 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. b

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, and smaller reporting company in Rule 12b-2 of the Exchange Act.

 Large accelerated filer b
 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 b

As of June 30, 2010, the aggregate market value of the registrant s common stock held by non-affiliates of the registrant was approximately \$17,638 million based on the closing sale price as reported on the New York Stock Exchange.

Common stock outstanding as of February 22, 2011 307,511,888 shares (including 1,834,765 shares held in treasury).

#### DOCUMENTS INCORPORATED BY REFERENCE

Part III of this report incorporates certain information by reference from the registrant s proxy statement for the annual meeting of stockholders to be held on May 3, 2011, which proxy statement will be filed no later than 120 days after the close of the registrant s fiscal year ended December 31, 2010.

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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, as amended and Section 21 of the Securities Exchange Act of 1934, as amended. 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, medical devices and over-the-counter products 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, biologics, 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 patients 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 2010, approximately 71% of our net product sales were derived from reimbursable products and 29% 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 2010, our research and development expenditures were approximately 16.7% of our product net sales or approximately \$804.6 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.

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*. Our Internet website address is not intended to function as a hyperlink and the information available at our website address is not incorporated by reference into this Annual Report on Form 10-K. 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 U.S. Securities and Exchange Commission, or SEC. The SEC maintains an Internet website 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 dry eye, glaucoma, retinal diseases and ocular surface disease;  $Botox^{\oplus}$  for certain therapeutic and aesthetic indications; skin care products for acne, psoriasis, eyelash growth and other prescription and over-the-counter skin care products; and 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*<sup>®</sup> 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, and segment operating income for our specialty pharmaceuticals segment and medical devices segment.

	2010	Ended December 3 2009 lollars in millions)	31, 2008
Specialty Pharmaceuticals Segment Product Net Sales by Product Line			
Eye Care Pharmaceuticals	\$ 2,262.0	\$ 2,100.6	\$ 2,009.1
<i>Botox</i> <sup>®</sup> /Neuromodulator	1,419.4	1,309.6	1,310.9
Skin Care	229.5	208.0	113.7
Urologics	62.5	65.6	68.6
Total Specialty Pharmaceuticals Segment Product Net Sales	\$ 3,973.4	\$ 3,683.8	\$ 3,502.3
Specialty Pharmaceuticals Segment Product Net Sales			
Domestic	63.6%	66.5%	65.2%
International	36.4%	33.5%	34.8%
Medical Devices Segment Product Net Sales by Product Line			
Breast Aesthetics	\$ 319.1	\$ 287.5	\$ 310.0
Obesity Intervention	243.3	258.2	296.0
Facial Aesthetics	283.8	218.1	231.4
Total Medical Devices Segment Product Net Sales	\$ 846.2	\$ 763.8	\$ 837.4
Medical Devices Segment Product Net Sales			
Domestic	57.9%	60.5%	62.0%
International	42.1%	39.5%	38.0%
Specialty Pharmaceuticals Segment Operating Income (1)	\$ 1,501.9	\$ 1,370.8	\$ 1,220.1
Medical Devices Segment Operating Income (1)	284.7	189.2	222.0
Consolidated Long-Lived Assets			
Domestic	\$ 3,222.4	\$ 3,678.3	\$ 3,785.4
International	688.1	572.3	549.4

(1) Management evaluates business segment performance on an operating income basis exclusive of general and administrative expenses and other indirect costs, legal settlement expenses, intangible asset impairment and related costs, restructuring charges, in-process research and development expenses, amortization of certain identifiable intangible assets related to business combinations and asset acquisitions and related capitalized licensing costs 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 17, Business Segment Information, in the notes to the consolidated financial statements listed under Item 15 of Part IV of this report, Exhibits and Financial Statement Schedules, for further information concerning our foreign and domestic operations.

#### **Specialty Pharmaceuticals Segment**

#### Eye Care Pharmaceuticals Product Line

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

#### Chronic Dry Eye

*Restasis*<sup>®</sup> (cyclosporine ophthalmic emulsion) 0.05% is the first, and currently the only, prescription therapy for the treatment of chronic dry eye worldwide. *Restasis*<sup>®</sup> 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*<sup>®</sup>, physicians used lubricating tears to provide palliative relief of the debilitating symptoms of chronic dry eye. We launched *Restasis*<sup>®</sup> in the United States in 2003 under a license from Novartis AG for the ophthalmic use of cyclosporine. During the third quarter of 2010, Health Canada approved *Restasis*<sup>®</sup> for the treatment of moderate to moderately severe aqueous deficient dry eye disease. *Restasis*<sup>®</sup> is currently approved in 41 countries.

Our over-the-counter artificial tears products, including the *Refresh*<sup>®</sup> and *Refresh*<sup>®</sup> *Optive* brands, treat dry eye symptoms including irritation and dryness due to pollution, computer use, aging and other causes. *Refresh*<sup>®</sup>, launched in 1986, 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*<sup>®</sup> and *Refresh*<sup>®</sup> *Optive* brands, were again the number one selling artificial tears products worldwide for the first nine months of 2010.

#### 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*<sup>®</sup> (bimatoprost ophthalmic solution) 0.03%, *Lumigan*<sup>®</sup> 0.01%, *Ganfort* (bimatoprost/timolol maleate ophthalmic solution), *Alphagan*<sup>®</sup> (brimonidine tartrate ophthalmic solution) 0.2%, or *Alphagan*<sup>®</sup>, *Alphagan*<sup>®</sup> P 0.15%, *Alphagan*<sup>®</sup> P 0.1% and *Combigan*<sup>®</sup> (brimonidine tartrate/timolol maleate ophthalmic solution) 0.2%/0.5%, captured approximately 26.2% of worldwide market sales in their product categories for first nine months of 2010.

*Lumigan*<sup>®</sup> 0.03% and *Lumigan*<sup>®</sup> 0.01% are topical treatments indicated for the reduction of elevated intraocular pressure in patients with glaucoma or ocular hypertension. *Lumigan*<sup>®</sup> 0.01% is an improved reformulation of *Lumigan*<sup>®</sup> 0.03%. We currently sell *Lumigan*<sup>®</sup> 0.01% and *Lumigan*<sup>®</sup> 0.03% in the United States and over 75 countries worldwide and, together, they are our second best selling eye care products. According to IMS Health Incorporated, *Lumigan*<sup>®</sup> 0.01% and *Lumigan*<sup>®</sup> 0.03% were amongst the best selling glaucoma products in the world for the first nine months of 2010. In 2002, the European Commission approved *Lumigan*<sup>®</sup>

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 U.S. Food and Drug Administration, or the FDA, approved *Lumigan*<sup>®</sup> 0.03% as a first-line therapy. We are party to an exclusive licensing agreement with Senju Pharmaceutical Co., Ltd., or Senju, under which Senju became responsible for the development and commercialization of *Lumigan*<sup>®</sup> 0.03% in Japan. In 2009, Senju received approval of *Lumigan*<sup>®</sup> 0.03% in Japan. Also in 2009, *Lumigan*<sup>®</sup> 0.01% was approved by Health Canada. In the first quarter of 2010, the European Commission granted a Marketing Authorization for *Lumigan*<sup>®</sup> 0.01% in the European Union member states. During the third quarter of 2010, the FDA approved *Lumigan*<sup>®</sup> 0.01% as a first-line therapy indicated for the reduction of elevated intraocular pressure in patients with open-angle glaucoma or ocular hypertension. In 2006, we received a license from the European Commission to market *Ganfort* in the European Union. *Ganfort* is now sold in over 37 countries outside the United States. Combined sales of *Lumigan*<sup>®</sup> 0.03%, *Lumigan*<sup>®</sup> 0.01% and 10% of our total consolidated product net sales in 2010, 2009 and 2008, respectively.

Our third best selling eye care products are the ophthalmic solutions  $Alphagan^{\otimes}$ ,  $Alphagan^{\otimes} P 0.15\%$  and  $Alphagan^{\otimes} P 0.1\%$ . These products lower intraocular pressure by reducing aqueous humor production and increasing uveoscleral outflow.  $Alphagan^{\otimes} P 0.15\%$  and  $Alphagan^{\otimes} P$ 0.1% are improved reformulations of  $Alphagan^{\otimes}$  containing brimonidine, the active ingredient in  $Alphagan^{\otimes}$ , preserved with  $Purite^{\otimes}$ . We currently market  $Alphagan^{\otimes}$ ,  $Alphagan^{\otimes} P 0.15\%$  and  $Alphagan^{\otimes} P 0.1\%$  in over 70 countries worldwide. In 2002, based on the acceptance of  $Alphagan^{\otimes} P 0.15\%$ , we discontinued the U.S. distribution of  $Alphagan^{\otimes}$ . We are party to an exclusive licensing agreement with Senju, under which Senju is responsible for the development and commercialization of  $Alphagan^{\otimes}$  and  $Alphagan^{\otimes} P 0.15\%$  in Japan. The marketing exclusivity period for  $Alphagan^{\otimes} P 0.1\%$  expired in 2008 and  $Alphagan^{\otimes} P 0.15\%$  now faces generic competition in the United States, although we have a number of patents covering the  $Alphagan^{\otimes} P 0.1\%$  and  $Alphagan^{\otimes} P 0.15\%$  technology that extend to 2022 in the United States. In 2003, the FDA approved the first generic of  $Alphagan^{\otimes}$ . Additionally, a generic form of  $Alphagan^{\otimes}$  is sold in a limited number of other countries, including Canada, Mexico, India, Brazil, Colombia, Argentina and in the European Union.

We also developed the ophthalmic solution *Combigan*<sup>®</sup>, a brimonidine and timolol combination designed to treat glaucoma and ocular hypertension in patients 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*<sup>®</sup> from 20 concerned member states included in the *Combigan*<sup>®</sup> Mutual Recognition Procedure for the European Union, and we launched *Combigan*<sup>®</sup> in the European Union during 2006. In 2007, the FDA approved *Combigan*<sup>®</sup> and we launched *Combigan*<sup>®</sup> in the United States. *Combigan*<sup>®</sup> is now sold in 67 countries worldwide. Combined sales of *Alphagan*<sup>®</sup>, *Alphagan*<sup>®</sup> P 0.15% and *Alphagan*<sup>®</sup> P 0.1% and *Combigan*<sup>®</sup> represented approximately 8%, 9% and 9% of our total consolidated product net sales in 2010, 2009 and 2008, respectively.

#### Inflammation

Our ophthalmic anti-inflammatory product  $Acuvail^{(0)}$  (ketorolac tromethamine ophthalmic solution) 0.45%, an advanced unit-dose preservative-free formulation of ketorolac for the treatment of pain and inflammation following cataract surgery, was approved by the FDA in 2009. Our ophthalmic anti-inflammatory product  $Acular LS^{(0)}$  (ketorolac ophthalmic solution) 0.4% is a version of  $Acular^{(0)}$  that has been reformulated for the reduction of ocular pain, burning and stinging following corneal refractive surgery.  $Acular^{(0)} PF$  was the first preservative-free topical non-steroidal anti-inflammatory drug in the United States.  $Acular^{(0)} PF$  is indicated for the reduction of ocular pain and photophobia following incisional refractive surgery. In 2009, the FDA approved seven Abbreviated New Drug Applications, or ANDAs, for ketorolac tromethamine ophthalmic solution 0.5%, a generic version of  $Acular^{(0)}$  and  $Acular LS^{(0)}$ .  $Acular^{(0)}$  and  $Acular LS^{(0)}$  now face generic competition. Our ophthalmic anti-inflammatory product  $Pred Forte^{(0)}$  remains a leading topical steroid worldwide based on 2010 sales. Pred Forte<sup>(0)</sup> has no patent protection or marketing exclusivity and faces generic competition.

<sup>4</sup> 

#### Infection

Our leading anti-infective is  $Zymar^{(0)}$  (gatifloxacin ophthalmic solution) 0.3%, which we license from Kyorin Pharmaceutical Co., Ltd. and have worldwide ophthalmic commercial rights excluding Japan, Korea, Taiwan and certain other countries in Asia and Europe. We launched  $Zymar^{(0)}$  in the United States in 2003.  $Zymar^{(0)}$  is a fourth-generation fluoroquinolone for the treatment of bacterial conjunctivitis and is currently approved in 33 countries. Laboratory studies have shown that  $Zymar^{(0)}$  kills the most common bacteria that cause eye infections as well as specific resistant bacteria. During the second quarter of 2010, we received FDA approval of  $Zymaxid^{(0)}$  (gatifloxacin ophthalmic solution) 0.5%, our next-generation anti-infective product indicated for the treatment of bacterial conjunctivitis. In February 2011, we announced the discontinuation of  $Zymar^{(0)}$  due to strong physician acceptance of  $Zymaxid^{(0)}$  with its increased concentration.

#### Allergy

The allergy market is, by its nature, a seasonal market, peaking during the spring months. We license *Elestat*<sup>®</sup> from Boehringer Ingelheim AG, and hold worldwide ophthalmic commercial rights excluding Japan. *Elestat*<sup>®</sup> is used for the prevention of itching associated with allergic conjunctivitis. We launched *Elestat*<sup>®</sup> in Europe under the brand names *Relestat*<sup>®</sup> and *Purivist*<sup>®</sup> during 2004, and Inspire Pharmaceuticals, Inc., or Inspire, our marketing partner in the United States, launched *Elestat*<sup>®</sup> during 2004. *Elestat*<sup>®</sup> (together with sales under its brand names *Relestat*<sup>®</sup> and *Purivist*<sup>®</sup>) is currently approved in 49 countries. In the third quarter of 2010, we acquired from Vistakon Pharmaceuticals, LLC, Janssen Pharmaceutica N.V., Beerse and Johnson & Johnson Vision Care Inc., or, collectively, Vistakon, the global license to manufacture and commercialize alcaftadine 0.25%, a topical allergy medication for the prevention and treatment of itching associated with allergic conjunctivitis. Alcaftadine is FDA-approved in the United States under the brand name *Lastacaft* (alcaftadine ophthalmic solution) and was commercialized in January 2011.

#### Retinal Disease

 $Ozurdex^{(0)}$  is a novel bioerodable formulation of dexamethasone in our proprietary *Novadur* sustained-release drug delivery system that can be used to locally and directly administer medications to the retina. In 2009, the FDA approved *Ozurdex*<sup>(0)</sup> (dexamethasone intravitreal implant) 0.7 mg, as the first drug therapy indicated for the treatment of macular edema associated with branch retinal vein occlusion or central retinal vein occlusion. We launched *Ozurdex*<sup>(0)</sup> in the United States in 2009. In the third quarter of 2010, the European Medicines Agency granted marketing authorization for *Ozurdex*<sup>(0)</sup> in the 27 member states of the European Union, making *Ozurdex*<sup>(0)</sup> the first licensed treatment in Europe for macular edema in patients with retinal vein occlusion. Also in the third quarter of 2010, the FDA approved *Ozurdex*<sup>(0)</sup> for the treatment of non-infectious occular inflammation, or uveitis, affecting the posterior segment of the eye.

#### Neuromodulator

#### Botox<sup>®</sup>

Our neuromodulator product, *Botox*<sup>®</sup> (onabotulinumtoxinA), has a long-established safety profile and has been approved by the FDA for more than 20 years to treat a variety of therapeutic conditions, as well as for aesthetic use since 2002. In 2010, therapeutic uses accounted for approximately 51% and aesthetic uses for approximately 49% of total sales. With more than 2,000 publications on *Botox*<sup>®</sup> and *Botox*<sup>®</sup> Cosmetic in scientific and medical journals, results of approximately 50 randomized, placebo-controlled clinical trials involving more than 11,000 patients, *Botox*<sup>®</sup> is a widely researched medicine with more than 100 potential therapeutic and aesthetic uses reported in the medical literature. Over 18 million treatment sessions have been recorded with *Botox*<sup>®</sup> and *Botox*<sup>®</sup> Cosmetic in the United States alone over the past 16 years (1994-2009). Marketed as *Botox*<sup>®</sup>, *Botox*<sup>®</sup> Cosmetic, *Vistabel*<sup>®</sup>, *Vistabex*<sup>®</sup> or *Botox Vista*<sup>®</sup> depending on the indication and country of approval, the product is currently approved in approximately 80 countries for up to 21 unique

indications. In 2009, following the approval of a competitor product, *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  $Botox^{(0)}$  represented approximately 29%, 29% and 30% of our total consolidated product net sales in 2010, 2009 and 2008, respectively.  $Botox^{(0)}$  has been primarily used therapeutically for the treatment of certain neuromuscular disorders which are characterized by involuntary muscle contractions or spasms as well as upper limb spasticity. In the fourth quarter of 2010, the FDA approved  $Botox^{(0)}$  for the prophylactic treatment of headaches in adults with chronic migraine. The approved therapeutic indications for  $Botox^{(0)}$  in the United States are as follows:

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

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

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

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

the treatment of increased muscle stiffness in the elbow, wrist and fingers in adults with upper limb spasticity; and

the prophylactic (preventative) treatment of headaches in adults with chronic migraine.

In many countries outside of the United States,  $Botox^{\oplus}$  is 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  $Botox^{\oplus}$  in the United States and Europe for new indications, including lower limb spasticity, neurogenic overactive bladder, idiopathic overactive bladder and benign prostatic hyperplasia. In the third quarter of 2010, we received approval for  $Botox^{\oplus}$  for the prophylactic treatment of headaches in adults with chronic migraine in the United Kingdom. In 2009, we submitted regulatory files for the use of  $Botox^{\oplus}$  to treat chronic migraine in France, Switzerland and Canada and are currently seeking approval in the European Union. In the fourth quarter of 2010, we filed a supplemental Biologics License Application, or sBLA, with the FDA for the use of  $Botox^{\oplus}$  in the treatment of urinary incontinence due to neurogenic detrusor overactivity resulting from neurogenic bladder and we are currently seeking approval in the European Union and Canada. In 2010, we completed enrollment in our Phase III clinical trials for the use of  $Botox^{\oplus}$  to treat idiopathic overactive bladder. In 2005, we initiated Phase II clinical trials outside the United States for the use of  $Botox^{\oplus}$  to treat benign prostatic hyperplasia. In 2009, we filed an Investigational New Drug Application with the FDA relating to the use of  $Botox^{\oplus}$  to treat benign prostatic hyperplasia.

#### Botox<sup>®</sup> Cosmetic

The FDA approved *Botox*<sup>®</sup> Cosmetic in 2002 for the temporary improvement in the appearance of moderate to severe glabellar lines in adult men and women age 65 or younger. Referred to as *Botox*<sup>®</sup>, *Botox*<sup>®</sup> Cosmetic, *Vistabel*<sup>®</sup>, *Vistabex*<sup>®</sup> or *Botox Vista*<sup>®</sup>, 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*<sup>®</sup>, *Botox*<sup>®</sup> Cosmetic, *Vistabel*<sup>®</sup>, *Vistabex*<sup>®</sup> or *Botox Vista*<sup>®</sup>. In Australia, New Zealand, Canada and certain countries in East Asia and Latin America, we have regulatory approvals for upper facial lines, including crow s feet. Since we have launched *Botox*<sup>®</sup> Cosmetic, we have conducted comprehensive direct-to-consumer marketing campaigns in the United States. We continue to sponsor aesthetic specialty physician training in approved countries to further expand the base of qualified physicians using *Botox*<sup>®</sup>, *Botox*<sup>®</sup> Cosmetic, *Vistabel*<sup>®</sup>, *Vistabex*<sup>®</sup> or *Botox Vista*<sup>®</sup>.

In 2005, we entered into a long-term arrangement with GlaxoSmithKline, or GSK, under which GSK agreed to develop and promote  $Botox^{\otimes}$  in Japan and China and we agreed to co-promote GSK s products *Imitrex STATdose System* (sumatriptan succinate) and *Amerge*<sup>®</sup> (naratriptan hydrochloride) in the United States until the third quarter of 2010. In the first quarter of 2010, we reacquired the rights from GSK to develop and sell *Botox*<sup>®</sup> in Japan and China for all current and future cosmetic indications. GSK retains the rights granted under the long-term arrangement to develop and sell *Botox*<sup>®</sup> in Japan and China for all current and future therapeutic indications. In 2009, *Botox*<sup>®</sup> was approved in Japan for the additional indications of glabellar lines and equinus foot due to lower limb spasticity in juvenile cerebral palsy patients and was launched in Japan for these indications with the glabellar lines indication marketed as *Botox*<sup>®</sup> in Japan for the treatment of upper and lower limb spasticity.

#### 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*<sup>®</sup> (dapsone) gel 5% is approved for sale in both the United States and Canada and is indicated for the treatment of acne vulgaris in patients age 12 and older. *Aczone*<sup>®</sup> contains the first new FDA-approved chemical entity (dapsone) for acne treatment since *Tazorac*<sup>®</sup> (tazarotene) gel was approved in 1997. We launched *Aczone*<sup>®</sup> in the United States in 2008. In February 2011, we outlicensed our Canadian rights to *Aczone*<sup>®</sup> to Biovail Laboratories International SRL, a subsidiary of Valeant Pharmaceuticals, Inc.

 $Tazorac^{(0)}$  (tazarotene) gel is approved for sale 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  $Tazorac^{(0)}$  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  $Zorac^{(0)}$  (tazarotene) in certain parts of Europe, the Middle East and Africa. In 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

 $Avage^{\otimes}$  (tazarotene) cream is indicated for the treatment of facial fine wrinkling, mottled hypo- and hyperpigmentation, or blotchy skin discoloration, and benign facial lentigines, or flat patches of skin discoloration, in patients using a comprehensive skin care and sunlight avoidance program. We launched  $Avage^{\otimes}$  in the United States in 2003.

We develop and market glycolic acid-based skin care products. We market our *M.D. Forte<sup>®</sup>* line of alpha hydroxy acid products to physicians in the United States.

*Prevage*<sup>®</sup> MD, containing 1% idebenone, which we launched in 2005, is 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. We market *Prevage*<sup>®</sup> MD to physicians in the United States.

 $Vivite^{\circ}$  is 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 *Vivite*<sup> $\circ$ </sup> line of skin care products to physicians in the United States. We launched *Vivite*<sup> $\circ$ </sup> in 2007.

#### Eyelash Growth

*Latisse*<sup>®</sup> (bimatoprost ophthalmic solution) 0.03%, is the first, and currently the only, FDA-approved prescription treatment of insufficient or inadequate eyelashes. The FDA approved *Latisse*<sup>®</sup> in 2008 and we launched *Latisse*<sup>®</sup> in the United States in 2009. *Latisse*<sup>®</sup> 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*<sup>®</sup> typically experience noticeable eyelash growth in eight to 16 weeks. Continued treatment with *Latisse*<sup>®</sup> is required to maintain its effect. *Latisse*<sup>®</sup> is also approved for sale in Canada and certain markets in Latin America and Asia Pacific.

#### Urologics

Following our 2007 acquisition of Esprit Pharma Holdings Company, Inc., or Esprit, we began marketing *Sanctura*<sup>®</sup>, a twice-a-day anticholinergic approved for the treatment of over-active bladder, or OAB. The FDA approved *Sanctura XR*<sup>®</sup>, a once-daily anticholinergic for the treatment of OAB in 2007 and we launched *Sanctura XR*<sup>®</sup> in 2008. *Sanctura XR*<sup>®</sup> 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*<sup>®</sup> and *Sanctura XR*<sup>®</sup> in the United States and its territories from Indevus Pharmaceuticals, Inc., which has since been acquired by Endo Pharmaceuticals, or Endo. We pay royalties to Endo based upon our sales of *Sanctura*<sup>®</sup>. In 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*<sup>®</sup> in Canada. In the first quarter of 2010, Health Canada approved *Sanctura XR*<sup>®</sup>. We promote *Sanctura XR*<sup>®</sup> to the urology specialty channel using our existing sales force in the United States. *Sanctura*<sup>®</sup> began facing generic competition in 2010.

#### **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<sup>®</sup>*, *Inspira<sup>®</sup>*, and *CUI* and the trademarks *BioCell<sup>®</sup>*, *MicroCell* and *BioDimensional<sup>®</sup>*. We currently market over 1,000 breast implant product variations worldwide to meet our patients preferences and needs.

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 the FDA and Health Canada in 2006, the U.S. and Canadian markets have been undergoing a transition from saline breast implants to silicone gel breast implants. The majority of the breast implants we now sell are silicone gel breast implants.

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 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 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 2011. In 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 in 2012. 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 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. We completed enrollment in BIFS in the first quarter of 2010.

In January 2011, the FDA released preliminary findings and analysis regarding recent reports in the scientific community that have suggested a possible association between saline and silicone gel-filled breast implants and anaplastic large cell lymphoma, or ALCL, a very rare form of cancer. The FDA believes that, based on its review of limited scientific data, women with breast implants may have a very small but increased risk of developing ALCL in the scar capsule adjacent to the implant. According to the FDA, a study by the National Cancer Institute indicates that only approximately 3 in 100 million women per year in the United States are diagnosed with ALCL in the breast, including both women with implants and without implants.

We sell a line of tissue expanders primarily for breast reconstruction and also 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 product is the *Juvéderm*<sup>®</sup> dermal filler family of products.

Our Juvéderm<sup>®</sup> dermal filler family of products, including Juvéderm<sup>®</sup>, Voluma and Surgiderm<sup>®</sup>, 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<sup>®</sup> Ultra and Ultra Plus, indicated for wrinkle and fold correction, for sale in the United States. In Europe, we market various formulations of Juvéderm<sup>®</sup>, Voluma and Surgiderm<sup>®</sup> for wrinkle and fold augmentation. The Juvéderm<sup>®</sup> dermal filler family of products are currently approved or registered in over 34 countries, including all major world markets with the exception of Japan and China where we are pursuing approvals.

In 2007, the FDA approved label extensions in the United States for *Juvéderm*<sup>®</sup> Ultra and Ultra Plus based on new clinical data demonstrating that the effects of both products may last for up to one year, which is a longer period of time than was reported in clinical studies that supported FDA approval of other hyaluronic acid dermal fillers. In 2008, we began selling *Juvéderm*<sup>®</sup> Ultra 2, 3 and 4, containing lidocaine, an anesthetic that alleviates pain during injections, in Europe. Also in 2008, we began selling *Juvéderm*<sup>®</sup> Ultra and Ultra Plus with lidocaine in Canada. After FDA approval in the first quarter of 2010, we launched *Juvéderm*<sup>®</sup> Ultra XC and Ultra Plus XC, each formulated with lidocaine, in the first quarter of 2010.

#### **Obesity Intervention**

#### Lap-Band®

We develop, manufacture and market several medical devices for the treatment of obesity. Our principal product in this area, the *Lap-Band*<sup>®</sup> System, is designed to provide minimally invasive long-term treatment of severe obesity and is used as an alternative to more invasive procedures such as gastric bypass surgery, sleeve gastrectomy, stapling or gastric imbrications. The *Lap-Band*<sup>®</sup> 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*<sup>®</sup> System has achieved widespread acceptance in the United States and worldwide. The FDA approved the *Lap-Band*<sup>®</sup> System in 2001 to treat severe obesity in adults who have failed more conservative weight reduction alternatives. In 2007, we launched the *Lap-Band AP*<sup>®</sup> System, a next-generation of the *Lap-Band*<sup>®</sup> System. The *Lap-Band AP*<sup>®</sup> System has proprietary 360-degree *Omniform*<sup>®</sup> technology, which is designed to evenly distribute pressure throughout the band s adjustment range. The *Lap-Band AP*<sup>®</sup> System 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 650,000 *Lap-Band*<sup>®</sup> System in patients aged 14 to 17 and submitted a sPMA to the FDA in 2009 seeking approval to market the *Lap-Band*<sup>®</sup> System for the treatment of obesity in patients aged 14 to 17. In February 2011, the FDA approved the expanded use of the *Lap-Band*<sup>®</sup> System for weight reduction in obese adults who have failed more conservative weight reduction alternatives and have a Body Mass Index, or BMI, of 30 to 40 and at least one comorbid condition, such as type-2 diabetes or hypertension.

#### Orbera

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, including many significant international markets, 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.

#### EasyBand

In 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. The EndoArt acquisition gave us ownership of EndoArt s proprietary technology platform, including *FloWatc*<sup>®</sup> technology, which powers the *EasyBand* Remote Adjustable Gastric Band System, or *EasyBand*, a telemetrically-adjustable gastric banding device for the treatment of morbid obesity. The *EasyBand*, like the *Lap-Band*<sup>®</sup> System, is implanted laparoscopically through a small incision. Clinical benefits of the *EasyBand* are similar to the *Lap-Band*<sup>®</sup> System s clinical benefits, except that adjustments to the *EasyBand* are done telemetrically rather than hydraulically.

#### **International Operations**

Our international sales represented 37.4%, 34.6% and 35.4% of our total consolidated product net sales for the years ended December 31, 2010, 2009 and 2008, 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 through our own sales subsidiaries in 36 countries and additionally 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 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, physiatrists, 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 2010, we also utilized direct-to-consumer advertising for our *Botox*<sup>®</sup> Cosmetic, *Juvéderm*<sup>®</sup>, the *Lap-Band*<sup>®</sup> System, *Latisse*<sup>®</sup>, *Natrelle*<sup>®</sup> and *Restasis*<sup>®</sup> 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, physiatrists, dermatologists, plastic and reconstructive surgeons, aesthetic specialty physicians, bariatric surgeons, pediatricians, urologists and general practitioners. As of December 31, 2010, we employed approximately 3,000 sales representatives throughout the world. 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 and surgeons with the leading techniques and methods for using our products.

We also utilize distributors for our products in smaller international markets. We transferred back sales and marketing rights for our products from our distributors and established direct operations in Poland and Turkey in the third quarter of 2010, and in the Philippines in the fourth quarter of 2010.

U.S. sales, including manufacturing operations, represented 62.6%, 65.4% and 64.6% of our total consolidated product net sales in 2010, 2009 and 2008, respectively. Sales to Cardinal Health, Inc. for the years ended December 31, 2010, 2009 and 2008 were 13.1%, 13.9% and 12.0%, respectively, of our total consolidated product net sales. Sales to McKesson Drug Company for the years ended December 31, 2010, 2009 and 2008 were 12.1%, 12.8% and 12.3%, respectively, of our total consolidated product net sales. No other country, or single customer, generated over 10% of our total consolidated product net sales.

#### **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, 2010, we had approximately 1,800 employees involved in our research and development efforts. Our research and development expenditures for 2010, 2009 and 2008 were approximately \$804.6 million, \$706.0 million and \$797.9 million, respectively. The increase in research and development expenses in 2010 compared to 2009 primarily resulted from increased spending on next-generation eye care

pharmaceuticals products for the treatment of glaucoma and retinal diseases,  $Latisse^{\circledast}$  in international markets,  $Botox^{\circledast}$  for the treatment of overactive bladder, hyaluronic-acid based dermal filler products, tissue regeneration technology acquired in our acquisition of Serica Technologies, Inc., or Serica, and obesity intervention products, partially offset by a reduction in expenses related to the development of  $Ozurdex^{\circledast}$  for retinal vein occlusion, the development of  $Botox^{\circledast}$  for the treatment of chronic migraine, and lower upfront payments for technology that has not achieved regulatory approval. Excluding in-process research and development expenditures related to company acquisitions, we have increased our annual investment in research and development by over \$416 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. In 2009, the FDA approved  $Ozurdex^{(0)}$  for the treatment of macular edema following retinal vein occlusion, 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 2010, the European Medicines Agency granted marketing authorization for  $Ozurdex^{(0)}$  in the European Union. In the third quarter of 2010, the FDA approved  $Ozurdex^{(0)}$  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  $Ozurdex^{\otimes}$  for the ophthalmic specialty market in Japan. Under the terms of the agreement, Sanwa is responsible for the development and commercialization of  $Ozurdex^{\otimes}$  in Japan and associated costs. Sanwa will pay us a royalty based on net sales of  $Ozurdex^{\otimes}$  in Japan, makes clinical development and commercialization milestone payments and reimbursed us for certain expenses associated with our Phase III studies outside of Japan. We are working collaboratively with Sanwa on the clinical development of  $Ozurdex^{\otimes}$  as well as overall product strategy and management.

In 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 retinal disorders.

We continue to invest heavily in the research and development of neuromodulators, primarily  $Botox^{\text{(B)}}$  and  $Botox^{\text{(B)}}$  Cosmetic. We focus on both expanding the approved indications for  $Botox^{\text{(B)}}$  and pursuing next-generation neuromodulator-based therapeutics. This includes expanding the approved uses for  $Botox^{\text{(B)}}$  to include treatment for spasticity, OAB and benign prostatic hyperplasia. We are also developing a new targeted neuromodulator for use in post herpetic neuralgia and overactive bladder. We are also continuing our investment in the areas of biologic process development and manufacturing and the next-generation of neuromodulator products, and we are conducting a Phase IV study of  $Botox^{\text{(B)}}$  for the treatment of palmar hyperhidrosis, as part of our conditions of approval for axillary hyperhidrosis by the FDA. In addition, GSK received approval of  $Botox^{\text{(B)}}$  in Japan for the treatment of glabellar lines and equinus foot due to lower limb spasticity in juvenile cerebral palsy patients and launched  $Botox^{\text{(B)}}$  in Japan for these indications in 2009 with the glabellar lines indication

marketed as *Botox Vista*<sup>®</sup>. GSK also received approval of *Botox*<sup>®</sup> in China for the treatment of glabellar lines during 2009. In the first quarter of 2010, we reacquired from GSK all rights to develop and sell *Botox*<sup>®</sup> in Japan and China for all cosmetic indications. In the third quarter of 2010, the Medicines and Healthcare Products Agency in the United Kingdom also approved *Botox*<sup>®</sup> for the preventative treatment of headaches in adults with chronic migraine. In the second quarter of 2010, the FDA approved *Botox*<sup>®</sup> for treatment of increased muscle stiffness in the elbow, wrist and fingers in adults with upper limb spasticity. In the fourth quarter of 2010, the FDA approved *Botox*<sup>®</sup> for preventative treatment of headaches in adults with chronic migraine. We also filed a sBLA with the FDA in the fourth quarter of 2010 for the use of *Botox*<sup>®</sup> in the treatment of urinary incontinence due to neurogenic detrusor overactivity resulting from neurogenic bladder and we are currently seeking approval in the European Union and Canada. In the fourth quarter of 2010, we also received approval of *Botox*<sup>®</sup> in Japan for the treatment of upper and lower limb spasticity.

In January 2011, we entered into a collaboration agreement and a co-promotion agreement with MAP Pharmaceuticals, Inc., or MAP, for the exclusive development and commercialization by us and MAP of *Levadex* within the United States to certain headache specialist physicians for the treatment of acute migraine in adults, migraine in adolescents 12 to 18 years of age and other indications that may be approved by the parties. *Levadex* is a self-administered, orally inhaled therapy consisting of a proprietary formulation of dihydroergotamine delivered using MAP s proprietary *Tempo* delivery system, which has completed Phase III clinical development for the treatment of acute migraine in adults.

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 *DATA* schoology 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 2009, we extended and expanded the scope of our collaboration with ExonHit.

In 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. Under the collaboration, Spectrum is conducting two Phase III clinical trials to explore apaziquone s safety and efficacy as a potential treatment for non-muscle invasive bladder cancer following surgery. In 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 III clinical trials in 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.

In the first quarter of 2010, we acquired Serica, 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 general surgical applications.

In the first quarter of 2010, we entered into a global agreement with Bristol-Myers Squibb Company, or Bristol-Myers Squibb, for the development and commercialization of AGN-209323, a Phase II-ready, orally administered small molecule in clinical development for neuropathic pain. Under the agreement, we received an upfront milestone payment and, if successful, will receive further milestone payments and royalties.

In the first quarter of 2010, we also entered into a strategic development and license agreement with Serenity Pharmaceuticals, LLC, or Serenity, for the development and commercialization of Ser-120, a Phase III investigational drug currently in clinical development for the treatment of nocturia, a urological disorder in adults characterized by frequent urination at night time. Under the agreement, we received an exclusive worldwide license to develop, manufacture and commercialize Ser-120 for all potential indications, except

under certain circumstances, pediatric bedwetting, which will remain with Serenity. In the third quarter of 2010, the Phase III clinical trials failed to meet their primary efficacy endpoints and we are currently evaluating a revised clinical plan.

We also continue to invest in research and development around our *Juvéderm*<sup>®</sup> family of dermal filler products, including preparation for and ongoing clinical trials for *Juvederm*<sup>®</sup> Voluma, a volumizing filler.

In connection with our obesity intervention products, we are conducting a clinical study of the *Orbera* System, with the goal of obtaining approval in the United States. In addition, in 2008, we completed enrollment in a pivotal adolescent study of *Lap-Band*<sup>®</sup> patients aged 14 to 17 and submitted a sPMA to the FDA in 2009 seeking approval to market the *Lap-Band*<sup>®</sup> System for the treatment of obesity in patients aged 14 to 17. In February 2011, the FDA approved the expanded use of the *Lap-Band*<sup>®</sup> System for weight reduction in obese adults who have failed more conservative weight reduction alternatives and have a BMI of 30 to 40 and at least one comorbid condition, such as type-2 diabetes or hypertension.

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 effect on our future operations.

#### Manufacturing

We manufacture the majority of our commercial products in our own plants located at the following locations: Westport, Ireland; Waco, Texas; San José, Costa Rica; Annecy, France; and Guarulhos, Brazil. In connection with our 2010 acquisition of Serica, we produce clinical supplies of biodegradable silk-based scaffolds at a leased facility in Massachusetts. We maintain sufficient manufacturing capacity at these facilities to support forecasted demand as well as a modest safety margin of additional capacity to meet peaks of demand and sales growth in excess of expectations. We increase our capacity as required in anticipation of future sales increases. In the event of a very large or very rapid unforeseen increase in market demand for a specific product or technology, supply of that product or technology could be negatively impacted until additional capacity is brought on line. Third parties manufacture a small number of commercial products for us, including *Sanctura<sup>®</sup>*, *Sanctura XR<sup>®</sup>*, *Lastacaft* and *Aczone<sup>®</sup>* 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 2007, we announced the closing of the collagen manufacturing facility in Fremont, California that we acquired in our acquisition of Inamed Corporation, or Inamed, and we substantially completed all restructuring activities and closed the facility in 2008. Before closing the facility, we manufactured a sufficient quantity of our collagen products to meet estimated remaining market demand. In 2009, we closed our Arklow, Ireland breast implant manufacturing facility and transferred manufacturing to our San José, Costa Rica manufacturing plant.

We are a vertically integrated producer 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  $Botox^{(0)}$ . With these two exceptions, we purchase all other significant raw materials and parts for medical devices 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 and parts for medical devices could adversely affect our ability to manufacture and supply commercial products. 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 principally compete on the basis of quality, clinical data, product design, an experienced sales force, physicians and surgeons familiarity with our products and brand names, effective marketing campaigns, including direct-to-consumer advertising, regional warranty programs and our ability to identify and develop or license patented products embodying new technologies. In addition to the information provided below, please see Item 3 of Part I of this report, Legal Proceedings, for information concerning current litigation regarding our products and intellectual property.

#### Specialty Pharmaceuticals Segment

#### Eye Care Products

Our eye care pharmaceutical products, including *Acular*<sup>®</sup>, *Acular LS*<sup>®</sup>, *Acular*<sup>®</sup> *PF*, *Acuvait*<sup>®</sup>, *Alocrit*<sup>®</sup>, *Alphagan*<sup>®</sup>, *Alphagan*<sup>®</sup>, *P* 0.15%, *Alphagan*<sup>®</sup> *P* 0.1%, *Combigan*<sup>®</sup>, *Elestat*<sup>®</sup>, *Ganfort, Lastacaft, Lumigan*<sup>®</sup> 0.03%, *Lumigan*<sup>®</sup> 0.01%, *Ozurdex*<sup>®</sup>, *Pred Forte*<sup>®</sup>, *Refresh*<sup>®</sup>, *Relestat*<sup>®</sup>, *Restasis*<sup>®</sup>, *Zymar*<sup>®</sup> and *Zymaxid*<sup>®</sup>, face extensive competition from Alcon Laboratories, Inc./Novartis AG, Bausch & Lomb Inc., Genentech/Hoffman La Roche AG, Inspire, Ista Pharmaceuticals, Inc., Merck & Co., Inc., 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 2010, *Alphagan® P* 0.15% and our *Acular®* products faced generic competition in the United States. A generic form of *Zymar®* produced by Apotex Inc. is pending FDA approval. The FDA has granted tentative approval of a generic form of *Elestat®* produced by Sandoz, Inc., PharmaForce, Inc. and Apotex Inc. but as of February 2011 no generic has been launched. In 2009, we received paragraph IV Hatch-Waxman Act certifications from Sandoz, Hi-Tech Pharmacal Co., and Alcon Research, Ltd., seeking FDA approval of generic forms of *Combigan®* and Barr Laboratories, Inc. seeking FDA approval of a generic form of *Lumigan®*. In February 2011, we received a paragraph IV Hatch-Waxman Act certification in which the applicant purports to have sought FDA approval of a generic form of *Zymaxid®*.

#### Neuromodulators

*Botox*<sup>®</sup> was the only neuromodulator approved by the FDA until 2000, when the FDA approved *Myobloc*<sup>®</sup> (rimabotulinumtoxinB), a neuromodulator formerly marketed by Elan Pharmaceuticals and Solstice Neurosciences Inc. and marketed by US Worldmeds since 2010. In 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*<sup>®</sup> 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 2008, Galderma became Ipsen s sole distributor for *Dysport* nor *Azzalure*. In the fourth quarter of 2010, Galderma announced its plan to acquire Q-Med A.B., a Swedish company that markets several products for various therapeutic areas derived from hyaluronic acid, including *Restylane*<sup>®</sup> and *Perlane* dermal fillers.

In addition, Merz Pharmaceuticals , or Merz s, botulinum toxin product *Xeominis* currently approved for therapeutic indications in Germany and several other countries in the European Union. *Xeominis* was approved by the FDA in the third quarter of 2010 for cervical dystonia and blepharospasm in adults previously treated with *Botox*. Merz is currently pursuing FDA approval of *Xeominis* for cosmetic use in the United States. In 2009, Merz received approval of *Bocouture* (rebranded from *Xeominis*) for glabellar lines in Germany. In 2010, *Bocouture* was approved in significant markets within the European Union. *Xeominis* is also approved for glabellar lines in Argentina and Mexico. In the first quarter of 2010, Merz acquired Bioform Medical Inc., or Bioform, a California-based company that markets *Radiesses*, a calcium hydroxylapatite filler. Merz also previously acquired rights from Anteis S.A., a Swiss company, to market *Belotero*, a hyaluronic acid filler, in certain European markets, the United States and Canada. The FDA accepted Merz s registration file for *Beloterb* in 2009.

Mentor Worldwide LLC, a division of Johnson & Johnson, or Mentor, is conducting clinical trials for a competing neuromodulator in the United States which Mentor has indicated that it expects to be approved in 2012 or beyond. A Korean botulinum toxin, *Meditoxin*<sup>®</sup>, 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*<sup>®</sup>. *Neuronox*<sup>®</sup> is marketed in Hong Kong, India and Thailand. *Meditoxin*<sup>®</sup> is approved in approximately seven South American countries, including Brazil and Columbia, under various trade names.

In addition, we are aware of competing neuromodulators currently being developed and commercialized in Asia, Europe, South America and other markets. A Chinese entity, Lanzhou Biological Institute, received approval to market a botulinum toxin in China in 1997 under the tradename HengLi, and has launched its botulinum toxin product in other lightly regulated markets in Asia, South America and Central America under

several trade names. 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*<sup>®</sup> 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®*, *Tazorac®*, *Avage®*, *M.D. Forte®*, *Prevage®* MD, *Vivite®* 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 AG, 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*<sup>®</sup> 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 *Detrôl*, *Detrol*<sup>®</sup> *LA* and *Toviaz*, Watson Pharmaceuticals, Inc. s *Oxytrôl* and *Gelnique*, Warner Chilcott PLC s *Enable* and Astellas Pharma US, Inc. and GSK s *Vesicar* and certain generic OAB products. We also face competition from generic urologic drug manufacturers in the United States and internationally. In 2009, we received paragraph 4 Hatch-Waxman Act certifications from Watson Pharmaceuticals, Inc. seeking FDA approval of a generic form of *Sanctura*  $XR^{®}$ . In 2010, a generic version of *Sanctura*<sup>®</sup> was launched in the United States. 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 2006 to sell its silicone breast implants in the United States. The conditions under which Mentor is allowed to market its silicone breast implants in the United States are similar to ours, including indications for use and the requirement to conduct post-marketing studies. If patients or physicians prefer Mentor s breast implant products to ours or perceive that Mentor s breast implant products are safer than ours, our sales of breast implants could materially suffer. In the United States, Sientra, Inc. is conducting clinical studies of saline and silicone gel breast implant products. Internationally, we compete with several manufacturers, including Mentor, Silimed, Arion, BioSil Ltd, Cereplas, Eurosilicone, Nagor, Poly Implant Prostheses, Polytech and several Chinese implant manufacturers.

#### **Obesity Intervention**

Ethicon Endo-Surgery, Inc., a subsidiary of Johnson & Johnson, received FDA approval in 2007 to market its gastric band product, the *Realize* Personalized Banding Solution, in the United States. The *Realize* band competes with our *Lap-Band*<sup>®</sup> System. Outside the United States, the *Lap-Band*<sup>®</sup> System competes primarily with the *Realize* band, Helioscopie SA s *Heliogast* adjustable gastric ring and Medical Innovation Developpement SAS s *Midband* gastric band. The *Lap-Band*<sup>®</sup> System also competes indirectly with surgical obesity procedures, including gastric bypass, vertical banded gastroplasty, sleeve gastrectomy, gastric imbrication and biliopancreatic diversion. No intragastric balloons for the treatment of obesity are commercially available in the United States. Outside the United States, our *Orbera* products compete with Helioscopie SA s *Heliospheri* and Spatz FGIA, Inc. 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*<sup>®</sup> Ultra and Ultra Plus, compete with Medicis products *Restylanend Perlane*, which were approved by the FDA in 2004 and in 2007, respectively. In the first quarter of 2010, the FDA approved our lidocaine containing *Juvéderm*<sup>®</sup> Ultra XC and Ultra Plus XC. In the first quarter of 2010, the FDA also approved new formulations of *Restylane*<sup>®</sup> and *Perlane* containing lidocaine. In addition, we compete with Merz s *Radiess*<sup>®</sup>, a calcium hydroxylapatite dermal filler from BioForm, which received FDA approval in 2006, as well as Sanofi-Aventis *Sculptra*<sup>®</sup> and Mentor s *Prevelle*Internationally, we compete with Q-Med s range of *Restylane*<sup>®</sup> and *Perlane* products, as well as products from Sanofi-Aventis, Teoxane, Anteis 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, and its implementing 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, expensive, and inherently uncertain. 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 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 a New Drug Application, or 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, a 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 IV studies, and surveillance programs to monitor the effect of approved products. The FDA may limit further marketing of the product based on the results of these post-market studies and programs. 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 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 and Department of Justice have 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 the European Medicines Agency and national Ministries of Health. 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 all 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. The recently enacted Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, collectively, the PPACA, imposes yet additional changes to these programs. Beginning in 2011, PPACA requires manufacturers to participate in a coverage gap discount program, under which they must agree to offer 50 percent point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer s outpatient drugs to be covered under Medicare Part D. PPACA also increases manufacturer s rebate liability under the Medicaid Drug Rebate Program. In addition, the PPACA establishes annual, non-deductible fees on any entity that manufactures or imports certain branded prescription drugs and biologics, beginning in 2011, and a deductible excise tax on any entity that manufactures or imports certain medical devices offered for sale in the United States, beginning in 2013. Already in 2010, incremental rebates were levied for Medicaid and the 340B program was expanded to extend manufacturers rebate responsibilities for outpatient drugs to additional providers, including certain children s hospitals, free-standing cancer hospitals, critical access hospitals, rural referral centers and sole community hospitals. Finally, 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, the United Kingdom, Turkey and Greece. 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 product candidates, including our breast implants, must undergo rigorous clinical testing and an extensive government regulatory clearance or 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 clearance or 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 to cease marketing and/or recall the modified device until 510(k) clearance or premarket approval is obtained.

In response to industry and healthcare provider concerns regarding the predictability, consistency and rigor of the 510(k) regulatory pathway, the FDA initiated an evaluation of the program, and in January 2011, announced 25 actions that the FDA intends to implement during 2011 to reform the review process governing the clearance of medical devices. Key actions, to be carried out through forthcoming FDA guidance to industry, include clarifying when clinical data should be included in a premarket submission and requiring medical device manufacturers to submit a brief description of scientific information regarding safety and effectiveness for select higher-risk devices. The FDA has submitted additional proposed actions to the Institute of Medicine, or IOM, for review and may implement further 510(k) reform measures in the future. We cannot predict the impact that these regulatory actions and FDA s forthcoming guidance will have on the clearance of any new or modified medical device products that are currently pending FDA review or that we may develop in the future.

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. As noted above, the FDA intends to clarify when clinical data should be included in 510(k) premarket submissions. Clinical 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 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

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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 in 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.

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, as mentioned in the previous section, the PPACA includes a number of provisions affecting the device industry, such as a new deductible excise tax on any entity that manufactures or imports certain medical devices offered for sale in the United States, beginning in 2013. In addition, among other things, the PPACA also establishes a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in and conduct comparative clinical effectiveness research. We expect that the PPACA, as well as other health care reform measures that may be adopted in the future, could have a material adverse effect on our industry generally and our ability to successfully commercialize our products or could limit or eliminate our spending on certain development projects.

#### **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 domestic and international laws and regulations 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. The risk of our being found in violation of these laws is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Moreover, recent health care reform legislation has strengthened these laws. For example, the PPACA, among other things, amends the intent requirement of the federal anti-kickback and criminal health care fraud statutes; a person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it. In addition, the PPACA provides that the government may assert that a claim including items or services resulting from a violation of the federal anti-kickback statute constitutes a false or fraudulent claim for purposes of the false claims statutes.

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. In the third quarter of 2010, we entered into a five-year corporate integrity agreement with the Office of Inspector General of the Department of Health and Human Services as part of our settlement agreement with the U.S. Attorney, U.S. Department of Justice for the Northern District of Georgia and other federal agencies regarding our alleged sales and marketing practices in connection with certain therapeutic uses of *Botox*<sup>®</sup>. Failure to comply with the terms of the corporate integrity agreement could result in substantial civil or criminal penalties and being excluded from government health care programs. 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).

Some states, such as California, Massachusetts and Vermont, mandate implementation of commercial compliance programs to ensure compliance with these laws. 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 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. In addition, certain states, such as Massachusetts and Minnesota, have also 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 have licenses under, numerous U.S. and foreign patents relating to our products, product uses and manufacturing processes. We believe that our patents and licenses are important to all segments of our business.

With the exception of the U.S. and European patents relating to Lumigan<sup>®</sup>, Lumigan<sup>®</sup> 0.01%, Alphagan<sup>®</sup> P 0.15%, Alphagan<sup>®</sup> P 0.1%, Combigan<sup>®</sup>, Ganfort and the U.S. patents relating to Restasis<sup>®</sup>, Zymaxid<sup>®</sup>, Acuvail<sup>®</sup>, Lastacaft and Latisse<sup>®</sup>, no one patent or license is materially important to our specialty pharmaceuticals segment. The U.S. patents covering Lumigan<sup>®</sup> 0.03% expire in 2012 and 2014. The European patents covering Lumigan<sup>®</sup> 0.03% expire in various countries between 2013 and 2017. The U.S. marketing exclusivity for Lumigan<sup>®</sup> 0.01% expires in August 2013. The U.S. patents covering Lumigan<sup>®</sup> 0.01% expire between 2013 and 2017, and 2026. The U.S. patents covering the commercial formulations of Alphagan<sup>®</sup> P 0.15%, and Alphagan<sup>®</sup> P 0.1% expire in 2012 and 2022. The U.S. patent covering Restasis<sup>®</sup> expires in 2014. One U.S. patent covering Zymar<sup>®</sup> and Zymaxid<sup>®</sup> expire in 2010, and the other U.S. patents covering Zymar<sup>®</sup> and Zymaxid<sup>®</sup> expire in 2022 and 2023. The marketing exclusivity period for Combigan<sup>®</sup> in the United States expired in October 2010 and expires in European patents covering Ganfort expire in 2013 and 2022. The user in 2013 and 2022. The user in 2013 and 2022. The user is in 2013 and 2020. The U.S. patents covering Zymar<sup>®</sup> and Zymaxid<sup>®</sup> expire in 2010, and the other U.S. patents covering Zymar<sup>®</sup> and Zymaxid<sup>®</sup> expire in 2016 and 2020. The U.S. patents covering Combigan<sup>®</sup> in the United States expired in October 2010 and expires in Europe in 2015. The European patents covering Acuvail<sup>®</sup> expires in 2029. The U.S. patents covering Latisse<sup>®</sup> expires in 2012, 2022 and 2024 and the European patents expires in 2013, 2021 and 2023. The marketing exclusivity period for Latisse<sup>®</sup> expires in December 2011.

We have rights in well over 100 issued  $Botox^{\text{@}}$  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 prostatic hyperplasia. We have granted royalty-bearing patent licenses to Merz with regard to *Xeomin*<sup>®</sup> in many countries where we have issued or pending patents and to US Worldmeds with regard to *MyoBloc*<sup>®</sup>/*Neurobloc*<sup>®</sup>.

With the exception of certain U.S. and European patents relating to the *Lap-Band*<sup>®</sup> System and our *Inspira*<sup>®</sup> and *Natrelle*<sup>®</sup> 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*<sup>®</sup> System, some of which we license from third parties, expire in June 2011, 2014 and 2024 in the United States and in 2014 and 2023 in Europe. The patents covering our *Inspira*<sup>®</sup> and *Natrelle*<sup>®</sup> 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 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, 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, but are not limited to, the following:

We entered into an exclusive licensing agreement with Kyorin under which Kyorin became responsible for the development and commercialization of  $Alphagan^{\text{(B)}}$  and  $Alphagan^{\text{(B)}} P 0.15\%$  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*<sup>®</sup> in Japan. Senju incurs associated costs, makes development and commercialization milestone payments and makes royalty-based payments on product sales. We are working collaboratively with Senju on overall product strategy and management. In 2009, Senju received approval of *Lumigan*<sup>®</sup> 0.03% in Japan.

We have licensed to GSK all clinical development and commercial rights to  $Botox^{(0)}$  for therapeutic indications in Japan and China. We receive royalties on GSK s Japan and China  $Boto^{(0)}$  sales. We also manufacture  $Botox^{(0)}$  for GSK as part of a long-term supply agreement. In the first quarter of 2010, we reacquired from GSK all rights to develop and sell  $Botox^{(0)}$  in Japan and China for all cosmetic indications. We market  $Botox^{(0)}$  in Japan for the glabellar lines indication as  $Botox Vista^{(0)}$ .

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 III clinical trials to explore apaziquone s safety and efficacy as a potential treatment for non-muscle invasive bladder cancer following surgery. In 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 III clinical trials in 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 the first quarter of 2010, we entered into an agreement with Bristol-Myers Squibb for the development and commercialization of an investigational drug for neuropathic pain. Under the terms of the agreement, we granted to Bristol-Myers Squibb exclusive worldwide rights to develop, manufacture, and commercialize the investigational drug for neuropathic pain and backup compounds.

In the first quarter of 2010, we entered into an agreement with Serenity for the development and commercialization of Ser-120, a nasally administered low dosage formulation of desmopressin currently in Phase III clinical trials for the treatment of nocturia, a common yet often under-diagnosed urological disorder in adults characterized by frequent urination at night time. We received an exclusive worldwide license to develop, manufacture and commercialize Ser-120 for all potential indications except, under certain circumstances, primary nocturnal enuresis (pediatric bedwetting). In 2010, the Phase III clinical trials failed to meet their primary efficacy endpoints and we are currently evaluating a revised clinical plan.

In the third quarter of 2010, we renegotiated our partnership with Inspire to revise Inspire s right to receive revenues from us based on net sales of *Restasis*<sup>®</sup> and any other human ophthalmic formulations of cyclosporine owned or controlled by us.

In January 2011, we entered into a collaboration agreement and a co-promotion agreement with MAP for the exclusive development and commercialization by us and MAP of *Levadex* within the United States to certain headache specialist physicians for the treatment of acute migraine in adults, migraine in adolescents 12 to 18 years of age and other indications that may be approved by the parties. *Levadex* is a self-administered, orally inhaled therapy consisting of a proprietary formulation of dihydroergotamine delivered using MAP s proprietary *Temp*<sup>®</sup> delivery system, which has completed Phase III clinical development for the treatment of acute migraine in adults.

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. See Research and Development for additional information concerning our current license agreements.

#### **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.

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  $Botox^{\oplus}$  product. Specifically, sales of  $Botox^{\oplus}$  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.  $Botox^{\oplus}$  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. Breast augmentation surgery has a seasonal highpoint in spring prior to summer vacations.

#### 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 2006, Medicare began covering certain designated bariatric surgical services, including gastric bypass surgery and procedures using the *Lap-Band*<sup>®</sup> System, for Medicare patients 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*<sup>®</sup> System product. For instance, the Technology Evaluation Center of the Blue Cross/Blue Shield National Association provided a positive assessment of the *Lap-Band*<sup>®</sup> System, an important step in providing private payor reimbursement for the procedure.

Outside the United States, reimbursement programs vary on a country by country basis. In some countries, both the procedure and product are fully reimbursed by the government 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, in March 2010, the President of the United States signed the PPACA, which substantially changes the way health care is financed by both governmental and private insurers, subjects biologic products to potential competition by lower-cost biosimilars, and significantly impacts the U.S. pharmaceutical and medical device industries. Among other things, the PPACA:

Establishes a licensure framework for biosimilar products;

Establishes a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in and conduct comparative clinical effectiveness research;

Increases minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program, retroactive to January 1, 2010, to 23.1 percent and 13 percent of the average manufacturer price, or AMP, for branded and generic drugs, respectively;

Expands manufacturers rebate responsibilities for outpatient drugs by extending the 340B program to additional providers including certain children s hospitals, free-standing cancer hospitals, critical access hospitals, rural referral centers and sole community hospitals, effective January 2010;

Extends manufacturers Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations, effective March 23, 2010;

Expands eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals beginning April 2010 and by adding new mandatory eligibility categories for certain individuals with income at or below 133 percent of the Federal Poverty Level beginning 2014, thereby potentially increasing manufacturers Medicaid rebate liability;

Redefines a number of terms used to determine Medicaid drug rebate liability, including average manufacturer price and retail community pharmacy, effective October 2010;

Requires manufacturers to participate in a coverage gap discount program, under which they must agree to offer 50 percent point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer s outpatient drugs to be covered under Medicare Part D, beginning January 2011;

Establishes annual, non-deductible fees on any entity that manufactures or imports certain branded prescription drugs and biologics, beginning January 2011; and

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Establishes a deductible excise tax on any entity that manufactures or imports certain medical devices offered for sale in the United States, beginning 2013.

The PPACA provisions on comparative clinical effectiveness research extend the initiatives of the American Recovery and Reinvestment Act of 2009, also known as the stimulus package, which included \$1.1 billion in

funding to study the comparative effectiveness of health care treatments and strategies. This funding was designated for, among other things, conducting, supporting or synthesizing research that compares and evaluates the risk and benefits, clinical outcomes, effectiveness and appropriateness of products. Although Congress has indicated that this funding is intended to improve the quality of health care, it remains unclear how the research will impact current Medicare coverage and reimbursement or how new information will influence other third-party payor policies. Though there have been initiatives to rescind the PPACA, we expect that its legislative measures, as well as other health care reform measures that may be adopted in the future, could have a material adverse effect on our industry generally and our ability to successfully commercialize our products or could limit or eliminate our spending on certain development projects.

#### **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, 2010, we employed approximately 9,200 persons throughout the world, including approximately 4,600 in the United States. None of our U.S.-based employees are represented by unions. We believe that our relations with our employees are generally good.

#### **Executive Officers**

Our executive officers and their ages as of February 28, 2011 are as follows:

Name	Age	Principal Positions with Allergan
David E.I. Pyott	57	Chairman of the Board and Chief Executive Officer
		(Principal Executive Officer)
F. Michael Ball	55	President, Allergan
James F. Barlow	52	Senior Vice President, Corporate Controller
		(Principal Accounting Officer)
Raymond H. Diradoorian	53	Executive Vice President, Global Technical Operations
Jeffrey L. Edwards	50	Executive Vice President, Finance and Business Development,
		Chief Financial Officer
		(Principal Financial Officer)
Samuel J. Gesten	49	Executive Vice President, General Counsel
Scott D. Sherman	45	Executive Vice President, Human Resources
Scott M. Whitcup, M.D.	51	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, where he serves as the lead independent director, 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 as a Vice Chairman of 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 as Chief Financial Officer of Wynn Oil Company, a division of Parker Hannifin Corporation. Prior to Wynn Oil Company, Mr. Barlow was Treasurer and Controller at Wynn s International, Inc., a supplier of automotive and industrial components and specialty chemicals, from July 1990 to September 2000. Before working for Wynn s International, Inc., Mr. Barlow was Vice President, Controller from 1986 to 1990 for Ford Equipment Leasing Company. From 1983 to 1985 Mr. Barlow worked for the accounting firm Deloitte Haskins and Sells.

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

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

Mr. Gesten has been Executive Vice President and General Counsel since August 2010. Mr. Gesten joined Allergan in June 2009 and served as Senior Vice President and General Counsel until July 2010. Prior to joining Allergan, Mr. Gesten spent 11 years with Thermo Fisher Scientific where he held various roles, including Vice President and General Counsel of the Laboratory Equipment Group and served on the group s leadership team. Mr. Gesten was also responsible for Thermo Fisher's corporate online legal training. Mr. Gesten has over 23 years of experience in the management of domestic and international legal affairs and leads Allergan's global team on all legal matters as well as supporting Allergan's Board of Directors and senior management. Mr. Gesten

is also the Vice-Chairman of the Allergan Political Action Committee for Employees. Mr. Gesten also serves as a member of the board of United Cerebral Palsy of Orange County.

Mr. Sherman joined Allergan as Executive Vice President, Human Resources in September 2010 with more than fifteen years of human resources leadership experience. Prior to joining Allergan, Mr. Sherman worked at Medtronic, Inc., a global medical device company, from August 1995 to September 2010 in roles of increasing complexity and responsibility. From April 2009 until September 2010, Mr. Sherman served as Medtronic s Vice President, Global Total Rewards and Human Resources Operations, where he was responsible for global compensation and benefits programs, and served as Secretary to the Compensation Committee of Medtronic s Board of Directors. Mr. Sherman lived in Europe from August 2005 until April 2009 and served as Vice-President, International Human Resources (May 2008 April 2009) and Vice-President, Human Resources Europe, Emerging Markets and Canada (August 2005 May 2008). Prior to these assignments, Mr. Sherman held a series of other positions at Medtronic including Vice President, Human Resources Diabetes (January 2002 July 2005). Prior to joining Medtronic, Mr. Sherman held various positions in the Human Resources and Sales organizations at Exxon Corporation from 1990 to 1995.

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 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.

#### Item 1A. Risk Factors

Before deciding to purchase, hold or sell our common stock, you should carefully consider the risks described below in addition to the other cautionary statements and risks described elsewhere and the other information contained in this report and in our other filings with the SEC, including subsequent Quarterly Reports on Forms 10-Q and Current Reports on Form 8-K. We operate in a rapidly changing environment that involves a number of risks. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also affect our business. These known and unknown risks could materially and adversely affect our business, financial condition, prospects, operating results or cash flows.

#### 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 and biological products. As discussed more fully below, such competition may increase in light of recent legislation providing a new regulatory pathway for the approval of lower-cost biosimilars. 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*<sup>®</sup>, *Botox*<sup>®</sup> Cosmetic, *Juvéderm*<sup>®</sup>, *Latisse*<sup>®</sup>, to a large extent the *Natrelle*<sup>®</sup> line of breast implants, and to a lesser extent the *Lap-Band*<sup>®</sup> 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. Sales of the *Lap-Band*<sup>®</sup> System appear to be adversely affected by high levels of unemployment in the United States. 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.

# 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 *Aczorfe*, *Sanctura*<sup>®</sup> 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*<sup>®</sup> 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*<sup>®</sup> 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 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 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:

the FDA may determine that the new indication or product candidate is not safe and effective;

the FDA may interpret our preclinical and clinical data in different ways than we do;

the FDA may not approve our manufacturing processes or facilities;

the FDA may not approve our risk evaluation and mitigation strategy, or 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. 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, pharmacovigilance or adverse event monitoring, 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 *Acuvail*<sup>®</sup>, *Aczone*<sup>®</sup>, *Alphagan*<sup>®</sup> P 0.15%, *Alphagan*<sup>®</sup> P 0.1%, *Botox*<sup>®</sup>, *Botox*<sup>®</sup> Cosmetic, *Combigan*<sup>®</sup>, *Elestat*<sup>®</sup>, *Ganfort, Juvéderm*<sup>®</sup>, the *Lap-Band*<sup>®</sup> System, *Latisse*<sup>®</sup>, *Lumigan*<sup>®</sup> 0.03%, *Lumigan*<sup>®</sup> 0.01%, *Optive, Ozurdex*<sup>®</sup>, *Refresh*<sup>®</sup>, *Relestat*<sup>®</sup>, *Restasis*<sup>®</sup>, *Sanctura XR*<sup>®</sup>, *Tazorac*<sup>®</sup>, and *Vistabel*<sup>®</sup>, as well as the *Natrelle*<sup>®</sup> line of breast implant products, new indications for *Botox*<sup>®</sup>, and new products such as *Lastacaft* and *Zymaxid*<sup>®</sup>. We cannot assure you that our currently marketed products will not be subject to further regulatory review and action.

In 2008, the FDA announced in an Early Communication its review of certain adverse events following the use of botulinum toxins, including  $Botox^{(0)}$  and  $Botox^{(0)}$  Cosmetic. In 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 2009, the FDA approved our REMS program for  $Botox^{(0)}$ , which addresses the risks related to botulinum toxin spread beyond the injection site and the lack of botulinum toxin interchangeability. In the second quarter of 2010, the FDA requested that we submit an update to the  $Botox^{(0)}$  Medication Guide to include the chronic migraine indication, updated REMS to include a physician training plan for chronic migraine, and a proposed physician communication, including a draft dear healthcare practitioner letter announcing the chronic migraine indication and providing information on the updated REMS. In the fourth quarter of 2010, the FDA approved *Botox*<sup>(0)</sup> for the prophylactic treatment of headaches in adults with chronic migraine. 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.

#### 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;

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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.

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. See Patents, Trademarks and Licenses in Item 1 of Part I of this report, Business and Item 3 of Part I of this report, Legal Proceedings for information concerning our current intellectual property and related litigation.

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

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*<sup>®</sup>, 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, rare lymphomas 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 explanation 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;

we monitor patients in our adjunct study through the patients 5-year evaluation; and

we conduct additional smaller evaluations, including a focus group aimed at ensuring patients are adequately informed about the risks of our silicone breast implants and that the format and content of patient labeling is adequate.

We are seeking marketing approval for other silicone breast implants in the United States, and if we obtain this approval, it may similarly be subject to significant restrictions and requirements, including the need for a patient registry, follow up MRIs and substantial post-market clinical trial commitments.

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

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# Negative publicity concerning the safety of our products may harm our sales, force us to withdraw products and cause a decline in our stock price.

Physicians and potential and existing patients may have a number of concerns about the safety of our products, including  $Botox^{\oplus}$ , breast implants, eye care pharmaceuticals, urologics products, skin care products, obesity intervention products and facial dermal fillers, whether or not such concerns have a basis in generally accepted science or peer-reviewed scientific research. These concerns may be increased by negative publicity, even if the publicity is inaccurate. For example, consumer groups and certain plaintiffs have alleged that certain uses of  $Botox^{\oplus}$ , including off-label uses, have caused patient injuries and death and have further alleged that we failed to adequately warn patients of the risks relating to  $Botox^{\oplus}$  use. In addition, recent reports have suggested a possible association between anaplastic large cell lymphoma, or ALCL, and breast implants. In January 2011, the FDA released preliminary findings and analysis regarding recent reports in the scientific community that have suggested a possible association between saline and silicone gel-filled breast implants and anaplastic large cell lymphoma, or ALCL, a very rare form of cancer. The FDA believes that, based on its review of limited scientific data, women with breast implants may have a very small but increased risk of developing ALCL in the scar capsule adjacent to the implant. Negative publicity whether accurate or inaccurate about the efficacy, safety or side effects of our products, cause consumers to seek alternatives to our products, result in product withdrawals and cause our stock price to decline. Negative publicity could also result in an increased number of product liability claims, whether or not these claims have a basis in scientific fact.

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

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

In addition, legislative and regulatory proposals and enactments to reform health care and government insurance programs could significantly influence the manner in which pharmaceutical products, biologic products and medical devices are prescribed and purchased. In March 2010, the President of the United States signed the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, collectively, the PPACA, which substantially changes the way health care is financed by both governmental and private insurers, subjects biologic products to potential competition by lower-cost biosimilars, and significantly impacts the U.S. pharmaceutical and medical device industries. Among other things, the PPACA:

Establishes a licensure framework for biosimilar products;

Establishes a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in and conduct comparative clinical effectiveness research;

Increases minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program, retroactive to January 1, 2010, to 23.1 percent and 13 percent of the average manufacturer price, or AMP, for branded and generic drugs, respectively;

Expands manufacturers rebate responsibilities for outpatient drugs by extending the 340B program to additional providers including certain children s hospitals, free-standing cancer hospitals, critical access hospitals, rural referral centers and sole community hospitals, effective January 2010;

Extends manufacturers Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations, effective March 23, 2010;

Expands eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals beginning April 2010 and by adding new mandatory eligibility categories for certain individuals with income at or below 133 percent of the Federal Poverty Level beginning 2014, thereby potentially increasing manufacturers Medicaid rebate liability;

Redefines a number of terms used to determine Medicaid drug rebate liability, including average manufacturer price and retail community pharmacy, effective October 2010;

Requires manufacturers to participate in a coverage gap discount program, under which they must agree to offer 50 percent point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer s outpatient drugs to be covered under Medicare Part D, beginning January 2011;

Establishes annual, non-deductible fees on any entity that manufactures or imports certain branded prescription drugs and biologics, beginning January 2011; and

Establishes a deductible excise tax on any entity that manufactures or imports certain medical devices offered for sale in the United States, beginning 2013.

The PPACA provisions on comparative clinical effectiveness research extend the initiatives of the American Recovery and Reinvestment Act of 2009, also known as the stimulus package, which included \$1.1 billion in funding to study the comparative effectiveness of health care treatments and strategies. This stimulus funding was designated for, among other things, conducting, supporting or synthesizing research that compares and evaluates the risks and benefits, clinical outcomes, effectiveness and appropriateness of products. The PPACA also appropriates additional funding to comparative clinical effectiveness research. Although Congress has indicated that this funding is intended to improve the quality of health care, it remains unclear how the research will impact current Medicare coverage and reimbursement or how new information will influence other third-party payor policies. We expect that the PPACA, as well as other health care reform measures that may be adopted in the future, could have a material adverse effect on our industry generally and our ability to successfully commercialize our products or could limit or eliminate our spending on certain development projects.

Title VII of the PPACA, the Biologics Price Competition and Innovation Act of 2009, or BPCIA, creates a new licensure framework for biosimilar products, which could ultimately subject our biologic products, including *Botox*<sup>®</sup>, to competition. Under the BPCIA, a manufacturer may submit an application for licensure of a biologic product that is biosimilar to or interchangeable with a referenced, branded biologic product. Previously, there had been no licensure pathway for such a follow-on product. While we do not anticipate that the FDA will license a biosimilar of *Botox*<sup>®</sup> for several years, given the need to generate data sufficient to demonstrate biosimilarity to or interchangeability with the branded biologic products, we note that the FDA held a public meeting in November, 2010 to seek stakeholder input on the subject and has the authority to approve biosimilar products whether or not the Agency first publishes guidance or promulgates regulations for biosimilar applicants. We cannot guarantee that our biologic products such as *Botox*<sup>®</sup> will not eventually become subject to direct competition by a licensed biosimilar.

Other legislative and regulatory reform measures, including the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or MMA, the Deficit Reduction Act of 2005, or DRA, and the Hospital Outpatient Prospective Payment System, or HOPPS, continue to significantly influence how our products are priced and reimbursed. For example, effective January 1, 2006, the MMA established a new Medicare outpatient prescription drug benefit under Part D. Further, among other things, the DRA required states to collect drug utilization data for single source drugs and certain multiple source drugs administered by physicians as a

condition of federal financial participation to be available for the drugs, and required the Centers for Medicare & Medicaid Services, or CMS, the federal agency that both administers the Medicare program and administers and oversees the Medicaid Drug Rebate Program, to amend certain formulas used to calculate pharmacy reimbursement and rebates under Medicaid and to publish final regulations. In July 2007, CMS issued a final rule that, among other things, clarifies and changes how drug manufacturers must calculate and report key pricing data under the Medicaid Drug Rebate Program. This data is used by CMS and state Medicaid agencies to calculate rebates owed by manufacturers under the Medicaid Drug Rebate Program and to calculate the federal upper limits on cost-sharing for certain prescription drugs. In December 2007, following a judicial challenge brought by a national association of pharmacies, a federal judge ordered an injunction that prevents CMS from implementing portions of its July 2007 final rule, as they affect Medicaid payments to pharmacies and the sharing by CMS of certain drug pricing data. In addition, the Medicare Improvements for Patients and Providers Act of 2008, or MIPPA, which was passed in July 2008, delayed the implementation dates of these portions of the July 2007 Medicaid final rule. The MIPPA prohibited the computation of Medicaid payments based on AMP and the public availability of AMP data through September 2009. The PPACA made certain changes that directly affect the provisions that were enjoined. Under the PPACA, key terms used for calculating manufacturer rebates and Medicaid payments for drugs, including AMP, have been redefined. The PPACA also made certain changes to establish adequate pharmacy reimbursement and limited the AMP information that may be publicly disclosed to weighted averages of multiple source drugs. These changes went into effect on October 1, 2010. At this time, uncertainties remain as to how the PPACA will be fully implemented and the extent to which such implementation could lead to reduced payments to pharmacies and others dispensing prescriptions for certain pharmaceutical products. These and other cost containment measures and health care reforms could adversely affect our ability to sell our products.

Furthermore, effective January 1, 2008, CMS reduced Medicare reimbursement for most separately payable physician-administered drugs under the hospital outpatient prospective payment system from an average sales price plus six percent to plus five percent. An additional reduction to average sales price plus four percent went into effect January 1, 2009, which continued for 2010. For calendar year 2011, CMS increased Medicare reimbursement to average sales price plus five percent, but further reductions may be imposed in the future.

Other recent federal regulatory changes include a final rule issued by the U.S. Department of Defense, or DoD, placing pricing limits on certain branded pharmaceutical products. Under the rule, effective May 26, 2009, payments made to retail pharmacies under the TRICARE Retail Pharmacy Program for prescriptions filled on or after January 28, 2008 are subject to certain price ceilings utilized by other DoD programs. Pursuant to the final rule and as a condition for placement on the Uniform Formulary, manufacturers are required, among other things, to modify their existing contracts with the DoD and to make refunds for prescriptions filled beginning on January 28, 2008 and extending to future periods based on the newly applicable price limits. The refunds required by the rule exempt certain prescriptions covered by manufacturer requests for a waiver. On October 15, 2010, the DoD issued a final rule, effective December 27, 2010, pursuant to which the DoD collects refunds as the means to subject prescriptions to the price ceilings and can take action against a manufacturer for failure to honor a requirement of the regulation or an agreement under the regulation. The new rule no longer penalizes manufacturers for failure to make an agreement with the DoD, because manufacturers may voluntarily elect not to participate in the TRICARE Pharmacy Benefits Program for any particular drug. Further, on October 26, 2010, the U.S. Government Accountability Office issued a report concluding that the DoD complied with the applicable procedural requirements in implementing the final rule. The issue of DoD s statutory authority to impose retroactive and prospective liability through refunds is on appeal.

In addition, individual states have also become increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access, and to encourage importation from other countries and bulk purchasing. Legally-mandated price controls on payment amounts by third-party payors or other restrictions could negatively and materially impact our revenues and financial condition.

We expect there will continue to be federal and state laws and/or regulations, proposed and implemented, that could limit the amounts that federal and state governments will pay for health care products and services. The extent to which future legislation or regulations, if any, relating to the health care industry or third-party coverage and reimbursement may be enacted or what effect such legislation or regulation would have on our business remains uncertain.

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

Our ability to sell our products to hospitals in the United States also depends in part on our relationships with group purchasing organizations, or GPOs. Many existing and potential customers for our products become members of GPOs. GPOs negotiate pricing arrangements and contracts, sometimes on an exclusive basis, with medical supply manufacturers and distributors, and these negotiated prices are made available to a GPO s affiliated hospitals and other members. If we are not one of the providers selected by a GPO, affiliated hospitals and other members may be less likely to purchase our products, and if the GPO has negotiated a strict sole source, market share compliance or bundling contract for another manufacturer s products, we may be precluded from making sales to members of the GPO for the duration of the contractual arrangement. Our failure to renew contracts with GPOs may cause us to lose market share and could have a material adverse effect on our sales, financial condition and results of operations. We cannot assure you that we will be able to renew these contracts at the current or substantially similar terms. If we are unable to keep our relationships and develop new relationships with GPOs, our competitive position would likely suffer.

We encounter similar legislative, regulatory and pricing issues in most countries outside the United States. International operations are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost-containment initiatives in Europe and other countries has and will continue to put pressure on the price and usage of our pharmaceutical and medical device products. Although we cannot predict the extent to which our business may be affected by future cost-containment measures or other potential legislative or regulatory developments, additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our current and future products, which could adversely affect our revenue and results of operations.

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

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

#### We are subject to risks associated with doing business internationally.

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

adverse changes in tariff and trade protection measures;

reductions in the reimbursement amounts we receive for our products from foreign governments and foreign insurance providers;

unexpected changes in foreign regulatory requirements, including quality standards and other certification requirements;

potentially negative consequences from changes in or interpretations of tax laws;

differing labor regulations;

changing economic conditions in countries where our products are sold or manufactured or in other countries;

differing local product preferences and product requirements;

exchange rate risks;

restrictions on the repatriation of funds;

political unrest and hostilities;

product liability, intellectual property and other claims;

differing quality control standards and assays;

new export license requirements;

differing degrees of protection for intellectual property; and

difficulties in coordinating and managing foreign operations, including ensuring that foreign operations comply with foreign laws as well as U.S. laws applicable to U.S. companies with foreign operations, such as export laws and the Foreign Corrupt Practices Act, or FCPA.

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

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

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

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

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

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

# Acquisitions of technologies, products, and businesses could disrupt our business, involve increased expenses and present risks not contemplated at the time of the transactions.

As part of our business strategy, we regularly consider and, as appropriate, make acquisitions of technologies, products and businesses that we believe are complementary to our business. Acquisitions typically entail many risks and could result in difficulties in integrating the operations, personnel, technologies and products acquired, some of which may result in significant charges to earnings. Issues that must be addressed in integrating the acquired technologies, products and businesses into our own include:

conforming standards, controls, procedures and policies, business cultures and compensation structures;

conforming information technology and accounting systems;

consolidating corporate and administrative infrastructures;

consolidating sales and marketing operations;

retaining existing customers and attracting new customers;

retaining key employees;

identifying and eliminating redundant and underperforming operations and assets;

minimizing the diversion of management s attention from ongoing business concerns;

coordinating geographically dispersed organizations;

managing tax costs or inefficiencies associated with integrating operations; and

making any necessary modifications to operating control standards to comply with the Sarbanes-Oxley Act of 2002 and the rules and regulations promulgated thereunder.

If we are unable to successfully integrate our acquisitions with our existing business, we may not obtain the advantages that the acquisitions were intended to create, which may materially adversely affect our business, results of operations, financial condition and cash flows, our ability to develop and introduce new products and the market price of our stock. Actual costs and sales synergies, if achieved at all, may be lower than we expect and may take longer to achieve than we anticipate. In connection with acquisitions, we could experience disruption in our business or employee base, or key employees of companies that we acquire may seek employment elsewhere, including with our competitors. Furthermore, the products of companies we acquire may overlap with our products or those of our customers, creating conflicts with existing relationships or with other commitments that are detrimental to the integrated businesses.

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

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

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

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

Even after we obtain regulatory approval or clearance for a product candidate or new indication, we are subject to extensive additional regulation, including implementation of REMS programs, completion of post-marketing clinical studies mandated by the FDA, and compliance with regulations relating to labeling, advertising, marketing and promotion, as well as regulations governing manufacturing controls noted above. In addition, we are subject to adverse event reporting regulations that require us to report to the FDA if our products are associated with a death or serious injury. If we or any third party that we involve in the testing, packaging, manufacture, labeling, marketing and distribution of our products fail to comply with any such regulations, we may be subject to, among other things, warning letters, product seizures, recalls, fines or other civil penalties, injunctions, suspension or revocation of approvals, operating restrictions and/or criminal prosecution.

In the past few years, the FDA has increased its enforcement activities related to the advertising and promotion of pharmaceutical, biological and medical device products. In particular, the FDA has expressed concern regarding the pharmaceutical and medical device industry s compliance with the agency s regulations and guidance governing direct-to-consumer advertising, and has increased its scrutiny of such promotional materials. The FDA may limit or, with respect to certain products, terminate our dissemination of direct-to-consumer advertisements in the future, which could cause sales of those products to decline. Physicians may prescribe pharmaceutical and biologic products, and utilize medical device products for uses that are not described in the product s labeling or differ from those tested by us and approved or cleared by the FDA. While such off-label uses are common and the FDA does not regulate a physician s practice of medicine, the FDA takes the position that a manufacturer s communications. For example, the FDA issued final guidelines on January 13, 2009 setting forth good reprint practices for drug and medical device manufacturers, which provide detailed requirements drug and device companies must follow when disseminating journal articles and referencing publications describing off-label uses of their approved products to health care professionals and entities. The standards associated with such laws and rules are complex, not well defined or articulated and are subject to conflicting interpretations. If, in the view of the FDA or other governmental agency, our promotional

activities fail to comply with applicable laws, regulations, guidelines or interpretations, we may be subject to enforcement actions by the FDA or other governmental enforcement authorities.

From time to time, legislative or regulatory proposals are introduced that could alter the review and approval process relating to our products. For example, in response to industry and healthcare provider concerns regarding the predictability, consistency and rigor of the 510(k) regulatory pathway, the FDA initiated an evaluation of the program, and on January 19, 2011, announced 25 actions that the FDA intends to implement during 2011 to reform the review process governing the clearance of medical devices. Among these actions, the FDA plans to issue multiple guidance to industry clarifying submission requirements. It is possible that the FDA or other governmental authorities will issue additional regulations further restricting the sale of our present or proposed products. Any change in legislation or regulations that govern the review and approval process relating to our current and future products could make it more difficult and costly to obtain approval for new products, or to produce, market and distribute existing products.

# Compliance with the requirements of domestic and international laws and regulations pertaining to the privacy and security of health information may be time consuming, difficult and costly, and if we are unable to or fail to comply, our business may be adversely affected.

We are subject to various domestic and international privacy and security regulations, 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, or 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 than HIPAA. Failure to comply with these laws can result in the imposition of significant civil and criminal penalties. The costs of compliance with these laws and potential liability associated with failure to do so could adversely affect our business, financial condition and results of operations.

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

The federal health care program Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce or in return for purchasing, leasing, ordering or arranging for the purchase, lease or order of any health care item or service reimbursable under Medicare, Medicaid or other federally financed health care programs. This statute has been interpreted to apply to arrangements between pharmaceutical or medical device manufacturers, on the one hand, and prescribers, purchasers and formulary managers, on the other hand. Further, the PPACA, among other things, amends the intent requirement of the federal anti-kickback and criminal health care fraud statutes. A person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it. In addition, the PPACA provides that the government may assert that a claim including items or services resulting from a violation of the federal anti-kickback statute constitutes a false or fraudulent claim for purposes of the false claims statutes. Although there are a number of statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution, the exemptions and safe harbors are drawn narrowly, and practices that involve remuneration could be subject to scrutiny if they do not qualify for an exemption or safe harbor.

The PPACA also imposes new reporting and disclosure requirements on device and drug manufacturers for any transfer of value made or distributed to prescribers and other healthcare providers, effective March 30, 2013. Such information will be made publicly available in a searchable format beginning September 30, 2013. In addition, device and drug manufacturers will also be required to report and disclose any investment interests held by physicians and their immediate family members during the preceding calendar year. Failure to submit required information may result in civil monetary penalties of up to an aggregate of \$150,000 per year (and up to an aggregate of \$1 million per year for knowing failures ), for all payments, transfers of value or ownership or

investment interests not reported in an annual submission. Finally, under the PPACA, effective April 1, 2012, pharmaceutical manufacturers and distributors must provide the U.S. Department of Health and Human Services with an annual report on the drug samples they provide to physicians.

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

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

The majority of states also have statutes or regulations similar to these federal laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. In addition, some states have laws that require pharmaceutical companies to adopt comprehensive compliance programs. For example, under California law, pharmaceutical companies must 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, as updated in July 2008 and effective in January 2009. 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 most recent revisions to the PhRMA Code, effective January 2009, restrict or prohibit many activities previously permissible under the prior PhRMA Code, including: a prohibition on any entertainment or recreational events for non-employee health care professionals including strict limitations on meals with physicians; the elimination of non-educational business gifts; restrictions on speaker programs; and clarifications on continuing medical education funding. The updated PhRMA Code also requires that pharmaceutical companies train their representatives on all applicable laws, regulations and industry codes governing interactions with health care professionals. In addition, 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; medical decisions are based on the best interests of patients; and medical device companies and health care professionals comply with applicable laws, regulations and government guidance. The AdvaMed Code was updated in December 2008 and became effective in July 2009. The revisions generally follow the 2008 changes in the PhRMA Code and include limitations on consulting arrangements, entertainment, and meals and gifts, among others. We have adopted and implemented a compliance program which we believe satisfies the requirements of these laws, regulations and industry codes.

Sanctions under these federal and state laws may include civil monetary penalties, mandatory compliance programs, exclusion of a manufacturer s products from reimbursement under government programs, criminal fines and imprisonment. Because of the breadth of these laws and the narrowness of the safe harbors, it is possible that some of our business activities could be subject to challenge under one or more of such laws. For example, we and several other pharmaceutical companies are currently subject to suits by governmental entities in several jurisdictions, including Erie, Oswego and Schenectady Counties in New York and in Alabama alleging that we and these other companies, through promotional, discounting and pricing practices, reported false and inflated average wholesale prices or wholesale acquisition costs and failed to report best prices as required by

federal and state rebate statutes, resulting in the plaintiffs overpaying for certain medications. If our past or present operations are found to be in violation of any of the laws described above or other similar governmental regulations to which we are subject, we may be subject to the applicable penalty associated with the violation which could adversely affect our ability to operate our business and our financial results.

We remain subject to government investigations and related subpoenas. Such subpoenas are often associated with previously filed qui tam actions, or lawsuits filed under seal under the False Claims Act, or FCA, 31 U.S.C. § 3729 et seq. Qui tam actions are brought by private plaintiffs suing on behalf of the federal government for alleged FCA violations. The time and expense associated with responding to such subpoenas, and any related qui tam or other actions, may be extensive, and we cannot predict the results of our review of the responsive documents and underlying facts or the results of such actions. The costs of responding to government investigations, defending any claims raised, and any resulting fines, restitution, damages and penalties (including under the FCA), settlement payments or administrative actions, as well as any related actions brought by stockholders or other third parties, could have a material impact on our reputation, business and financial condition and divert the attention of our management from operating our business.

In September 2009, we received service of process of an Investigative Demand from the Department of Justice for the State of Oregon requesting the production of documents relating to our sales and marketing practices in connection with  $Aczone^{\text{®}}$ . In December 2009, we produced documents in response to the Investigative Demand.

In June 2010, we received service of process of a Subpoena from the U.S. Securities and Exchange Commission. The subpoena requests the production of documents relating to our affiliation with Acadia Pharmaceuticals, Inc., or Acadia, and our sale of Acadia securities. In September 2010, we produced documents responsive to the Subpoena. In January 2011, the SEC issued additional Subpoenas seeking further information, which was provided in February 2011.

In December 2010, we received service of process of a Subpoena Duces Tecum from the State of New York, Office of the Medicaid Inspector General. The subpoena requests the production of documents relating to our Eye Care Business Advisor Group, Allergan Access, and BSM Connect for Ophthalmology.

In February 2011, we received service of a Civil Investigative Demand from the United States Attorney s Office for the Southern District of New York, Civil Frauds Unit. The Investigative Demand requests the production of documents and responses to written interrogatories relating to our best prices provided to Medicaid for certain of our ophthalmic products.

In March 2008, we received service of a Subpoena Duces Tecum from the U.S. Attorney, U.S. Department of Justice, or DOJ, for the Northern District of Georgia requesting the production of documents relating to our sales and marketing practices in connection with certain therapeutic uses of  $Botox^{\oplus}$ . In September 2010, we announced that we reached a resolution with the DOJ, or the DOJ Settlement, regarding our alleged sales and marketing practices in connection with certain therapeutic uses of  $Botox^{\oplus}$ . As part of the DOJ Settlement, we entered into a five-year Corporate Integrity Agreement with the Office of Inspector General of the Department of Health and Human Services. Failure to comply with the terms of the Corporate Integrity Agreement could result in substantial civil or criminal penalties and being excluded from government health care programs, which could materially reduce our sales and adversely affect our financial condition and results of operations.

#### We could be adversely affected by violations of the U.S. Foreign Corrupt Practices Act and similar worldwide anti-bribery laws.

We are subject to the FCPA, which generally prohibits companies and their intermediaries from making payments to non-U.S. government officials for the purpose of obtaining or retaining business or securing any other improper advantage. We are also subject to anti-bribery laws in the jurisdictions in which we operate. Although we have policies and procedures designed to ensure that we, our employees and our agents comply with the FCPA and other anti-bribery laws, there is no assurance that such policies or procedures will protect us against liability under the FCPA or other laws for actions taken by our agents, employees and intermediaries with

respect to our business or any businesses that we acquire. We do business in a number of countries in which FCPA violations have recently been enforced. Failure to comply with the FCPA, other anti-bribery laws or other laws governing the conduct of business with foreign government entities, including local laws, could disrupt our business and lead to severe criminal and civil penalties, including imprisonment, criminal and civil fines, loss of our export licenses, suspension of our ability to do business with the federal government, denial of government reimbursement for our products and exclusion from participation in government health care programs. Other remedial measures could include further changes or enhancements to our procedures, policies, and controls and potential personnel changes and/or disciplinary actions, any of which could have a material adverse affect on our business, financial condition, results of operations and liquidity. We could also be adversely affected by any allegation that we violated such laws.

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

We have entered into collaborative arrangements with third parties to develop and market certain products, including our collaboration with MAP Pharmaceuticals, Inc to develop and commercialize *Levadex* in the United States, our strategic development and license agreement with Serenity Pharmaceuticals, LLC, or Serenity, for the development and commercialization of Ser-120, our agreement with Stiefel to develop and commercialize new products that include tazarotene, our collaboration with Spectrum for the development and commercialization of apaziquone and our agreement with Bristol-Myers Squibb for the development of an investigational neuropathic pain medicine. We cannot assure you that these collaborations will be successful, lead to additional sales of our products or lead to the creation of additional products. For instance, in 2010, Serenity s Phase III clinical trials for the development and commercialization of Ser-120 failed to meet their primary efficacy endpoints and we are currently evaluating a revised clinical plan. If we fail to maintain our existing collaborative arrangements or fail to enter into additional collaborative arrangements, our licensing revenues and/or the number of products from which we could receive future revenues could decline.

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

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

We are subject to income taxes in both the United States and numerous foreign jurisdictions. Our effective tax rate could be adversely affected by changes in the mix of earnings in countries with different statutory tax rates, changes in the valuation of deferred tax assets and liabilities, changes in tax laws and regulations, changes in our interpretations of tax laws, including pending tax law changes, changes in our manufacturing activities and changes in our future levels of research and development spending. In that regard, there have been a number of recent proposals, including by Congress and the Treasury as well as various government appointed and outside commissions, that could substantially impact the U.S. taxation of U.S.-based multinational corporations such as Allergan. In addition, we are subject to the continuous examination of our income tax returns by the Internal Revenue Service and other local, state and foreign tax authorities. We regularly assess the likelihood of outcomes resulting from these examinations to determine the adequacy of our estimated income tax liabilities. There can be

no assurance that the outcomes from these continuous examinations will not have an adverse effect on our provision for income taxes and estimated income tax liabilities.

Changes in applicable tax laws may adversely affect sales or the profitability of  $Botox^{\$}$ ,  $Botox^{\$}$  Cosmetic, our dermal fillers or breast implants. Because  $Botox^{\$}$  and  $Botox^{\$}$  Cosmetic are pharmaceutical products and our dermal fillers and breast implants are medical devices, we generally do not collect or pay state sales or other tax on sales of  $Botox^{\$}$ ,  $Botox^{\$}$  Cosmetic, our dermal fillers or our breast implants. We could be required to collect and pay state sales or other tax associated with prior, current or future years on sales of  $Botox^{\$}$ ,  $Botox^{\$}$  Cosmetic, our dermal fillers or breast implants. In addition to any retroactive taxes and corresponding interest and penalties that could be assessed, if we were required to collect or pay state sales or other tax associated with current or future years on sales of  $Botox^{\$}$ ,  $Botox^{\$}$  Cosmetic, our dermal fillers or breast implants, our sales of, or our profitability from,  $Botox^{\$}$ ,  $Botox^{\$}$  Cosmetic, our dermal fillers or breast implants could be adversely affected due to the increased cost associated with those products.

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

Our total indebtedness as of December 31, 2010 was approximately \$2,204.8 million. This indebtedness may limit our flexibility in planning for, or reacting to, changes in our business and the industry in which it operates and, consequently, place us at a competitive disadvantage to our competitors. The operating and financial restrictions and covenants in our debt agreements may adversely affect our ability to finance future operations or capital needs or to engage in new business activities. For example, our debt agreements restrict our ability to, among other things, incur liens or engage in sale lease-back transactions and engage in consolidations, mergers and asset sales.

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

#### Litigation may harm our business or otherwise distract our management.

Substantial, complex or extended litigation could cause us to incur large expenditures and distract our management. For example, lawsuits by employees, stockholders, customers or competitors could be very costly and substantially disrupt our business. Disputes from time to time with such companies or individuals are not uncommon, and we cannot assure you that we will always be able to resolve such disputes out of court or on terms favorable to us. See Item 3 of Part I of this report, Legal Proceedings and Note 13, 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.

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

The reports of publicly-traded companies are subject to review by the SEC from time to time for the purpose of assisting companies in complying with applicable disclosure requirements and to enhance the overall effectiveness of companies public filings, and comprehensive reviews of such reports are now required at least

every three years under the Sarbanes-Oxley Act of 2002. SEC reviews may be initiated at any time. While we believe that our previously filed SEC reports comply, and we intend that all future reports will comply in all material respects with the published rules and regulations of the SEC, we could be required to modify or reformulate information contained in prior filings as a result of an SEC review. Any modification or reformulation of information contained in such reports could be significant and could result in material liability to us and have a material adverse impact on the trading price of our common stock.

Item 1B. Unresolved Staff Comments

None.

# Item 2. Properties

Our operations are conducted in owned and leased facilities located throughout the world. We believe our present facilities are adequate for our current needs. Our headquarters and primary administrative and research facilities, which we own, are located in Irvine, California. We own and lease additional facilities in California to provide administrative, research and raw material support, manufacturing, warehousing and distribution. We own one facility in Texas for manufacturing and warehousing. In connection with our 2010 acquisition of Serica, we produce clinical supplies of biodegradable silk-based scaffolds at a leased facility in Massachusetts.

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

#### Item 3. Legal Proceedings

We are involved in various lawsuits and claims arising in the ordinary course of business.

#### Clayworth v. Allergan, et al.

In August 2004, James Clayworth, R.Ph., doing business as Clayworth Pharmacy, filed a complaint entitled Clayworth v. Allergan, et al. in the Superior Court of the State of California for the County of Alameda. The complaint, as amended, named us and 12 other defendants and alleged unfair business practices, including a price fixing conspiracy relating to the reimportation of pharmaceuticals from Canada. The complaint sought damages, equitable relief, attorneys fees and costs. In January 2007, the court entered a notice of entry of judgment of dismissal against the plaintiffs, dismissing the plaintiffs complaint. On the same date, the plaintiffs filed a notice of appeal with the Court of Appeal of the State of California. In April 2007, the plaintiffs filed an opening brief with the court of appeal. The defendants filed their joint opposition in July 2007, and the plaintiffs filed their reply in August 2007. In May 2008, the court of appeal heard oral arguments and took the matter under submission. In July 2008, the court of appeal affirmed the superior court s ruling, granting our motion for summary judgment. In August 2008, the plaintiffs filed a petition for rehearing with the court of appeal, which the court denied. In September 2008, the plaintiffs filed a petition for review with the Supreme Court of the State of California, which the supreme court granted in November 2008. In February 2009, the plaintiffs filed their opening brief on the merits with the supreme court and defendants filed their answer brief in May 2009. In June 2009, the plaintiffs filed their reply brief on the merits with the supreme court. In May 2010, the supreme court heard oral arguments. In July 2010, the supreme court reversed the court of appeal s judgment and remanded the case to the superior court for further proceedings. In October 2010, plaintiffs filed a challenge to the assignment of this matter to the presiding judge alleging a conflict of interest. In November 2010, plaintiffs challenge was denied. In December 2010, plaintiffs filed a petition for writ of mandate in the Court of Appeal of the State of California seeking to overturn the order denying their challenge. In December 2010, the court of appeal denied the petition. In December 2010, plaintiffs filed a petition for review with the Supreme Court of the State of California. In January 2011, the court set trial for August 1, 2011. In February 2011, the supreme court denied plaintiffs petition for review.

Allergan, Inc. v. Cayman Chemical Company, et al.

In November 2007, we filed a complaint captioned Allergan, Inc. v. Cayman Chemical Company, Jan Marini Skin Research, Inc., Athena Cosmetics, Inc., Dermaquest, Inc., Intuit Beauty, Inc., Civic Center Pharmacy and Photomedex, Inc. in the U.S. District Court for the Central District of California. In the complaint, we allege that the defendants are infringing U.S. Patent No. 6,262,105 licensed to us by Murray A. Johnstone, M.D. In January 2008, we filed a motion for leave to file a second amended complaint to add Dr. Johnstone, the holder of U.S. Patent No. 6,262,105, as a plaintiff and to add Global MDRx and ProCyte Corporation, or ProCyte, as defendants. In March 2008, the court granted the motion for leave to file a second amended complaint. In April 2008, we filed a motion for leave to file a third amended complaint to add patent infringement claims relating to U.S. Patent No. 7,351,404 against the defendants, and to add Athena Bioscience, LLC and Cosmetic Alchemy, LLC as additional defendants.

In 2008, we entered into settlement agreements with Jan Marini Skin Research, Inc., Intuit Beauty, Inc., Photomedex, Inc. and ProCyte pursuant to which each party agreed to acknowledge the validity of the patents in exchange for dismissing all claims against such defendant. In July 2008, the clerk of the court entered a default judgment against Global MDRx for failure to defend against the summons. In August 2008, the court dismissed Intuit Beauty, Inc. and Jan Marini Skin Research, Inc. with prejudice. In September 2008, we and Cayman Chemical Company entered into a settlement agreement under which Cayman Chemical Company agreed to cease selling certain compounds to be used in particular types of products in exchange for dismissing all claims against them. In December 2008, we entered into a settlement agreement with Athena Bioscience, LLC under which they agreed to cease selling certain products and acknowledged the validity of our patents in exchange for our dismissing all claims against them.

In January 2009, we, along with Dr. Johnstone, filed a motion for leave to file a fourth amended complaint adding Pharma Tech, Inc., Dimensional Merchandising, Inc. and Cosmetic Technologies, Inc. as new defendants. In February 2009, we, along with Dr. Johnstone, filed a motion for default judgment and injunction against Global MDRx and the court granted our motion. In April 2009, we and Cosmetic Technologies, Inc. entered into a settlement agreement under which Cosmetic Technologies, Inc. agreed to cease manufacturing and selling certain products and acknowledge the validity of our patents in exchange for our dismissing all claims against them.

In March 2009, we filed a complaint captioned Allergan, Inc.; Murray A Johnstone, M.D.; and Duke University v. Athena Cosmetics, Inc.; Cosmetic Alchemy, LLC; Northwest Cosmetic Laboratories, LLC; Pharma Tech International, Inc.; Dimensional Merchandising, Inc.; Stella International, LLC; Product Innovations, LLC; Metrics, LLC; Nutra-Luxe M.D., LLC; Skin Research Laboratories, Inc.; Lifetech Resources LLC; Rocasuba, Inc.; Peter Thomas Roth Labs LLC; and Peter Thomas Roth, Inc. in the U.S. District Court for the Central District of California alleging infringement of U.S. Patent Nos. 6,262,105, 7,351,404, and 7,388,029. In June 2009, we and defendants La Canada Ventures, Inc. and Susan Lin, M.D. entered into a settlement agreement under which La Canada Ventures, Inc. and Susan Lin, M.D. agreed to cease manufacturing and selling certain products and acknowledge the validity of our patents in exchange for our dismissing all claims against La Canada Ventures, Inc. and Susan Lin, M.D.

In June 2009, the court consolidated Allergan, Inc.; Murray A Johnstone, M.D.; and Duke University v. Athena Cosmetics, Inc., *et al.* with Allergan, Inc. v. Cayman Chemical Company, *et al.* and set an October 2010 trial date for both cases. In October 2009, the defendants filed answers, amended answers and/or counterclaims to our first amended complaint. In February 2010, we and Athena Cosmetic, Inc. filed a stipulation with the court to bifurcate Athena Cosmetic, Inc. s antitrust and Lanham Act counterclaims into separate trials. In February 2010, Athena Cosmetic, Inc., Pharma Tech and Northwest Cosmetic filed a motion for judgment on the pleadings regarding our claim for violation of the California unfair competition statute. In March 2010, the court granted Athena Cosmetic, Inc., Pharma Tech and Northwest Cosmetic s motion for judgment on the pleadings. In May 2010, we entered into a settlement agreement with Nutra-Luxe M.D., LLC, under which Nutra-Luxe M.D., LLC

agreed to cease manufacturing and selling certain products and acknowledge the validity of our patents in exchange for our dismissing all claims against them. In May 2010, pursuant to a stipulation filed by the plaintiffs and all defendants against whom there are currently claims pending in the two consolidated actions, the court entered an order stating that a final judgment will be entered on the dismissal of our unfair competition claim against the defendants, permitting us to appeal the dismissal without further delay to the U.S. Court of Appeals for the Federal Circuit, and further stating that all U.S. District Court proceedings in both consolidated actions will be stayed pending completion of our appeal of the dismissal of our unfair competition claim. In May 2010, we filed a notice of appeal with the court of appeals. In August 2010, we filed a motion for summary reversal or, in the alternative, for expedited treatment with the court of appeals and defendants filed an opposition to our motion. In October 2010, the court of appeals denied our motion for summary reversal, or in the alternative, for expedited treatment. In January 2011, the court of appeals scheduled oral argument for March 9, 2011.

#### Kramer et al. v. Allergan, Inc.

In July 2008, a complaint entitled Kramer, Bryant, Spears, Doolittle, Clark, Whidden, Powell, Moore, Hennessey, Sody, Breeding, Downey, Underwood-Boswell, Reed-Momot, Purdon & Hahn v. Allergan, Inc. was filed in the Superior Court for the State of California for the County of Orange. The complaint makes allegations against us relating to  $Botox^{(0)}$  and  $Botox^{(0)}$  Cosmetic including failure to warn, manufacturing defects, negligence, breach of implied and express warranties, deceit by concealment and negligent misrepresentation and seeks damages, attorneys fees and costs. In 2009, the plaintiffs Hennessey, Hahn, Underwood-Boswell, Purdon, Moore, Clark, Reed-Momot and Whidden were dismissed without prejudice. In October 2009, we filed a motion for summary judgment against plaintiff Spears, which the court denied in December 2009. The trial related to plaintiff Spears began in January 2010. In March 2010, the jury returned a verdict in our favor and the court entered a judgment on the special verdict. In April 2010, plaintiff Spears filed a motion for a new trial which the court denied in May 2010. In June 2010, we and plaintiff Spears entered into a settlement agreement under which we agreed to waive costs in exchange for plaintiff Spears agreeing not to appeal the judgment. In September 2010, the trial related to plaintiff Bryant. In January 2011, the court set the next trial for September 6, 2011.

#### Alphagan<sup>®</sup> P Patent Litigation

In February 2007, we received a paragraph 4 invalidity and noninfringement Hatch-Waxman Act certification from Exela PharmSci, Inc., or Exela, indicating that Exela had filed an Abbreviated New Drug Application, or ANDA, with the U.S. Food and Drug Administration, or the FDA, for a generic form of *Alphagan*<sup>®</sup> *P* 0.15%. In the certification, Exela contends that U.S. Patent Nos. 5,424,078, 6,562,873, 6,627,210, 6,641,834 and 6,673,337, all of which are assigned to us and are listed in the Orange Book under *Alphagan*<sup>®</sup> *P* 0.15%, are invalid and/or not infringed by the proposed Exela product. In March 2007, we filed a complaint against Exela in the U.S. District Court for the Central District of California entitled Allergan, Inc. v. Exela PharmSci, Inc., *et al.*, or the Exela Action. In our complaint, we allege that Exela s proposed product infringes U.S. Patent No. 6,641,834. In April 2007, we filed an amended complaint adding Paddock Laboratories, Inc. and PharmaForce, Inc. as defendants.

In April 2007, we received a paragraph 4 invalidity and noninfringement Hatch-Waxman Act certification from Apotex Inc., or Apotex, indicating that Apotex had filed ANDAs with the FDA for generic versions of *Alphagan*<sup>®</sup> *P* 0.15% and *Alphagan*<sup>®</sup> *P* 0.1%. In the certification, Apotex contends that U.S. Patent Nos. 5,424,078, 6,562,873, 6,627,210, 6,641,834 and 6,673,337, all of which are assigned to us and are listed in the Orange Book under *Alphagan*<sup>®</sup> *P* 0.15% and *Alphagan*<sup>®</sup> *P* 0.1%, are invalid and/or not infringed by the proposed Apotex products. In May 2007, we filed a complaint against Apotex in the U.S. District Court for the District of Delaware entitled Allergan, Inc. v. Apotex Inc. and Apotex Corp., or the Apotex Action. In our complaint, we allege that Apotex s proposed products infringe U.S. Patent Nos. 5,424,078, 6,562,873, 6,627,210, 6,641,834 and 6,673,337. In June 2007, Apotex filed its answer, including defenses and counterclaims. In July 2007, we filed a response to Apotex s counterclaims.

In May 2007, we filed a motion with the multidistrict litigation panel to consolidate the Exela Action and the Apotex Action in the District of Delaware. In August 2007, the panel granted the motion and transferred the Exela Action to the District of Delaware for coordinated or consolidated pretrial proceedings with the Apotex Action. In March 2008, the defendants in the Exela Action consented to trial in Delaware. In January 2009, we and defendants Paddock Laboratories, Inc. and Pharmaforce, Inc. entered into a settlement agreement under which these defendants agreed to refrain from selling or manufacturing a generic version of  $Alphagan^{\oplus} P 0.15\%$  in exchange for our dismissing all claims against them. Trial was held in March 2009 for the remaining defendants in the Apotex Action and the Exela Action. In October 2009, the court ruled that all five patents (U.S. Patent Nos. 5,424,078, 6,562,873, 6,627,210, 6,641,834 and 6,673,337) asserted by us are valid and enforceable against the defendants, that Apotex s proposed generic versions of Alphagan P 0.1% and 0.15% infringe each of the five patents, and that Exela s proposed generic version of Alphagan P 0.15% infringes U.S. Patent No. 6,641,834, which was the only patent asserted against it. Pursuant to the Hatch-Waxman Act, the FDA is required to delay approval of defendants proposed generic products until after our last applicable patent expires in 2022. In November 2009, Apotex and Exela filed their opening briefs with the court of appeals. In May 2010, we filed our responsive briefs with the court of appeals. In March 2010, Apotex and Exela filed their reply briefs with the court of appeals. In November 2010, the court of appeals scheduled oral argument for January 10, 2011. On January 10, 2011, the court of appeals heard oral argument and took the matter under submission.

#### Zymar<sup>®</sup> Patent Litigation

In October 2007, we received a paragraph 4 invalidity and noninfringement Hatch-Waxman Act certification from Apotex, indicating that Apotex had filed an ANDA with the FDA for a generic version of *Zymar*<sup>®</sup>. In the certification, Apotex contends that U.S. Patent Nos. 5,880,283 and 6,333,045, or the 045 patent, both of which are licensed to us and are listed in the Orange Book under *Zyma*<sup>®</sup>, are invalid and/or not infringed by the proposed Apotex product. In November 2007, we, Senju Pharmaceutical Co., Ltd., or Senju, and Kyorin Pharmaceutical Co., Ltd., or Kyorin, filed a complaint captioned Allergan, Inc., Senju Pharmaceutical Co., Ltd. and Kyorin Pharmaceutical Co., Ltd. v. Apotex Inc., *et al.* in the U.S. District Court for the District of Delaware. The complaint alleges infringement of the 045 patent. In January 2008, Apotex filed an answer and a counterclaim, as well as a motion to partially dismiss the plaintiffs complaint. In February 2008, we, Senju and Kyorin filed a response of non-opposition to Apotex s motion to partially dismiss the complaint. A three-day bench trial was conducted in January 2010. In March and April 2010, the parties filed their post-trial briefs. In June 2010, the court further ruled that Apotex failed to prove that claims 6 and 7 are invalid for lack of enablement and that claims 1-3 and 6-9 are invalid as obvious. The court further ruled that Apotex failed to prove that claims 6 and 7 are invalid for lack of enablement and that Apotex failed to prove that the 045 patent and findings regarding claim 7. In July 2010, Apotex filed an answer to our motion and we filed a reply to Apotex s answer to our motion. In November 2010, the court dismissed our motion for a new trial without prejudice to renew and opened the record of the litigation so that additional evidence may be submitted.

In August 2010, we filed a statement of claim entitled Allergan, *et al.* & Kyorin Pharmaceutical Co., LTD v. Apotex Inc., *et al.* in the Federal Court of Canada at Ottawa, Ontario, Canada. The statement of claim alleges that Apotex s product infringes Canadian Patent No. 1,340,316 covering *Zymar*<sup>®</sup>. In September 2010, Apotex filed a motion to strike the statement of claim. In November 2010, the court dismissed the motion to strike. In November 2010, Apotex filed a notice of appeal regarding the dismissed motion to strike.

#### Combigan<sup>®</sup> Patent Litigation

In February 2009 and April 2009, we received paragraph 4 invalidity and noninfringement Hatch-Waxman Act certifications from Sandoz, Inc., or Sandoz, and Hi-Tech Pharmacal Co. Inc., or Hi-Tech, respectively, indicating that Sandoz and Hi-Tech had filed ANDAs seeking approval of generic forms of *Combigan*<sup>®</sup>, a

brimonidine tartrate 0.2%, timolol 0.5% ophthalmic solution. In their separate certifications, Sandoz and Hi-Tech each contend that U.S. Patent Nos. 7,030,149 and 7,320,976, listed in the Orange Book under *Combigan*<sup>®</sup>, are invalid and/or not infringed by the proposed Sandoz product and by the proposed Hi-Tech product. We filed complaints against Sandoz and Hi-Tech in the U.S. District Court for the Eastern District of Texas in April 2009 and June 2009, respectively, alleging, in each case, that the defendant s proposed product infringes U.S. Patent Nos. 7,030,149 and 7,320,976. In June 2009, Sandoz filed a motion to dismiss and we filed a response to this motion in July 2009. In July 2009, Hi-Tech filed a motion to dismiss and we filed a response to this motion to dismiss. In October 2009, Hi-Tech filed a reply to our response. In October 2009, we filed a motion to consolidate the Hi-Tech action and the Sandoz action and the court granted our motion to consolidate the two actions. In November 2009, Hi-Tech withdrew its motion to dismiss.

In September 2009, we received a paragraph 4 invalidity and noninfringement Hatch-Waxman Act certification from Alcon Research, Ltd., or Alcon, indicating that Alcon had filed an ANDA seeking approval of a generic version of *Combigan*<sup>®</sup>. In the certification, Alcon contends that U.S. Patent Nos. 7,030,149, 7,320,976 and 7,323,463, listed in the Orange Book under *Combigan*<sup>®</sup>, are invalid and/or not infringed by the proposed Alcon product. In November 2009, we filed a complaint against Alcon in the U.S. District Court for the Eastern District of Texas, Marshall Division. The complaint alleges that Alcon s proposed product infringes U.S. Patent Nos. 7,030,149, 7,320,976 and 7,323,463.

In October 2009 and November 2009, we received amended paragraph 4 invalidity and noninfringement Hatch-Waxman Act certifications from Sandoz and Hi-Tech, respectively, indicating that Sandoz and Hi-Tech had filed ANDAs seeking approval of generic forms of *Combigan*<sup>®</sup>. In their separate certifications, Sandoz and Hi-Tech each contend that U.S. Patent No. 7,323,463, listed in the Orange Book under *Combigan*<sup>®</sup>, is invalid and/or not infringed by the proposed Sandoz and Hi-Tech products. In November 2009, we filed an amended complaint against Sandoz and Hi-Tech for patent infringement to assert U.S. Patent No. 7,323,463. Sandoz filed an answer and counterclaims to our amended complaint in November 2009 and Hi-Tech filed an answer and counterclaims in December 2009. We filed an answer to Sandoz s counterclaims in December 2009 and an answer to Hi-Tech s counterclaims in January 2010. In January 2010, the Hi-Tech action and the Sandoz action were consolidated with the Alcon action.

In February 2010, we received amended paragraph 4 invalidity and noninfringement Hatch-Waxman Act certifications from Sandoz and Hi-Tech indicating that Sandoz and Hi-Tech had filed ANDAs seeking approval of generic forms of *Combigan*<sup>®</sup>. In their separate certifications, Sandoz and Hi-Tech contend that U.S. Patent No. 7,642,258, listed in the Orange Book under *Combigan*<sup>®</sup>, is invalid and/or not infringed by the proposed Sandoz and Hi-Tech products. In March 2010, we filed a second amended complaint against Sandoz and Hi-Tech for patent infringement to assert U.S. Patent No. 7,642,258. Hi-Tech and Sandoz filed an answer and counterclaims to our second amended complaint in March 2010 and April 2010, respectively. In April 2010, we filed answers to Hi-Tech and Sandoz s counterclaims. In April 2010, we received an amended paragraph 4 invalidity and noninfringement Hatch-Waxman Act certification from Alcon indicating that Alcon had filed an ANDA seeking approval of a generic form of *Combigan*<sup>®</sup>. In their certification, Alcon contends that U.S. Patent No. 7,642,258, listed in the Orange Book under *Combigan*<sup>®</sup>, is invalid and/or not infringed by the proposed Alcon product. In April 2010, we filed a first amended complaint against Alcon for patent infringement to assert U.S. Patent No. 7,642,258. In May 2010, Alcon filed an answer and counterclaims to our first amended complaint. In June 2010, we filed an answer to Alcon s counterclaims. The court has scheduled an August 1, 2011 trial date for the consolidated Hi-Tech, Sandoz and Alcon actions.

In May 2010, we received a paragraph 4 invalidity and noninfringement Hatch-Waxman Act certification from Apotex Corp. and Apotex indicating that Apotex had filed an ANDA seeking approval of a generic version of *Combigan*<sup>®</sup>. In the certification, Apotex contends that U.S. Patent Nos. 7,030,149, 7,320,976, 7,323,463 and 7,642,258 listed in the Orange Book under *Combigan*<sup>®</sup>, are invalid and/or not infringed by the proposed Apotex product. In June 2010, we filed a complaint against Apotex in the U.S. District Court for the Eastern District of

Texas, Marshall Division. The complaint alleges that Apotex s proposed product infringes U.S. Patent Nos. 7,030,149, 7,320,976, 7,323,463 and 7,642,258. In June 2010, we filed an amended complaint. In July 2010, Apotex filed an answer and counterclaims to our first amended complaint. In August 2010, we filed an answer to Apotex s counterclaims. In September 2010, the Hi-Tech action, the Sandoz action, and the Alcon action were consolidated with the Apotex action.

In July 2010, we received a paragraph 4 invalidity and noninfringement Hatch-Waxman Act certification from Watson Laboratories, Inc., Watson Pharma, Inc. and Watson Pharmaceuticals, Inc., or Watson, indicating that Watson had filed an ANDA seeking approval of a generic version of *Combigan*<sup>®</sup>. In the certification, Watson contends that U.S. Patent Nos. 7,030,149, 7,320,976, 7,323,463 and 7,642,258, listed in the Orange Book under *Combigan*<sup>®</sup>, are invalid and/or not infringed by the proposed Watson product. In September 2010, we filed a complaint against Watson in the U.S. District Court for the Eastern District of Texas, Marshall Division. The complaint alleges that Watson s proposed product infringes U.S. Patent Nos. 7,030,149, 7,320,976, 7,323,463, and 7,642,258. In October 2010, Watson filed an unopposed motion to dismiss without prejudice Watson Pharmaceuticals, Inc. and Watson Pharma, Inc., which the court granted. In October 2010, Watson filed an answer to the complaint and counterclaims. In November 2010, we filed an answer to Watson s counterclaims. In February 2011, the court scheduled a November 4, 2013 trial date for the Watson action.

In December 2009, we received a Notice of Allegation letter from Sandoz Canada Inc., or Sandoz Canada, indicating that Sandoz Canada had filed an Abbreviated New Drug Submission, or ANDS, under paragraphs 5(1)(b)(iii), 5(1)(b)(iv) and 5(3) of the Patented Medicines (Notice of Compliance) Regulations for approval of a generic version of *Combigan*<sup>®</sup> (DIN 02248347). In the letter, Sandoz Canada contends that Canadian Patent Nos. 2,173,974, 2,225,626 and 2,440,764 are invalid and/or not infringed by the proposed Sandoz Canada product. In February 2010, we filed a notice of application in the Canadian Federal Court. The application alleges that Sandoz Canada indicating that Sandoz Canada had filed an ANDS under paragraphs 5(1)(b)(iii), 5(1)(b)(iv) and 5(3) of the Patented Medicines (Notice of Compliance) Regulations for approval of a generic version of *Combigan*<sup>®</sup>. In the letter, Sandoz Canada contends that Canadian Patent No. 2,357,014 is invalid and/or not infringed by the proposed Sandoz Canada indicating that Sandoz Canada product. In March 2010, we filed a notice of application in the Canadian product. In March 2010, we filed a notice of application in the Canadian Federal Court. The application alleges that Sandoz Canada indicating that Sandoz Canada infringed by the proposed Sandoz Canada product. In March 2010, we filed a notice of application in the Canadian Federal Court. The application alleges that Sandoz Canada s proposed product infringes Canadian Patent No. 2,357,014. In May 2010, Sandoz Canada filed two motions to strike the application regarding Canadian Patent No. 2,225,626. In November 2010, the court denied Sandoz Canada s first motion to strike. In August 2010, we entered into an agreement to discontinue our notice of application relating to Canadian Patent No. 2,357,014 in exchange for Sandoz Canada s withdrawing its pending motion to strike the application regarding Canadian Patent No. 2,225,626. In November 2010, the court set the trial in this case for October 24, 2011.

In August 2010, we received a Notice of Allegation letter from Apotex Canada Inc., or Apotex Canada, indicating that Apotex Canada had filed an ANDS under paragraphs 5(1)(b)(iii), 5(1)(b)(iv) and 5(3) of the Patented Medicines (Notice of Compliance) Regulations for approval of a generic version of *Combigan*<sup>®</sup> (DIN 02248347). In the letter, Apotex Canada contends that Canadian Patent Nos. 2,173,974, 2,225,626, 2,357,014 and 2,440,764 are invalid and/or not infringed by the proposed Apotex Canada product. In September 2010, we filed a notice of application in the Canadian Federal Court. The application alleges that Apotex Canada s proposed product infringes Canadian Patent Nos. 2,225,626, 2,357,014 and 2,440,764. In December 2010, the court set the trial in this case for November 28, 2011.

#### Sanctura XR® Patent Litigation

In June 2009, we received a paragraph 4 invalidity and noninfringement Hatch-Waxman Act certification from Watson, through its subsidiary Watson Laboratories, Inc. Florida, indicating that Watson had filed an ANDA seeking approval of a generic form of *Sanctura X* $\hat{R}$ , trospium 60 mg. chloride extended release capsules. In the certification, Watson contends that U.S. Patent No. 7,410,978, listed in the Orange Book under *Sanctura X* $\hat{R}$ <sup>®</sup>, is invalid and/or not infringed by the proposed Watson product.

In July 2009, we, Endo Pharmaceuticals Solutions, Inc., or Endo, and Supernus Pharmaceuticals, Inc., or Supernus, filed a complaint against Watson, Watson Laboratories, Inc. Florida, and Watson Pharma, Inc. in the U.S. District Court for the District of Delaware. The complaint alleges that Watson s proposed product infringes U.S. Patent No. 7,410,978. In August 2009, Watson filed an answer and counterclaims to our complaint. In September 2009, we filed an answer to Watson s counterclaims.

In November 2009, we received a paragraph 4 invalidity and noninfringement Hatch-Waxman Act certification from Sandoz indicating that Sandoz had filed an ANDA seeking approval of a generic form of *Sanctura XR*<sup>®</sup>, trospium 60 mg. chloride extended release capsules. In the certification, Sandoz contends that U.S. Patent No. 7,410,978, listed in the Orange Book under *Sanctura XR*<sup>®</sup>, is invalid and/or not infringed by the proposed Sandoz product. In November 2009, we, Endo and Supernus filed a complaint against Sandoz in the U.S. District Court for the District of Delaware. The complaint alleges that Sandoz s proposed product infringes U.S. Patent No. 7,410,978. In January 2010, Sandoz filed an answer and counterclaims to our complaint. In February 2010, we filed an answer to Sandoz s counterclaims. In March 2010, the court consolidated the Watson and Sandoz actions and scheduled a trial date for May 2, 2011.

In April 2010, we received a paragraph 4 invalidity and noninfringement Hatch-Waxman Act certification from Paddock Laboratories, Inc., or Paddock, indicating that Paddock had filed an ANDA seeking approval of a generic form of *Sanctura XR*<sup>®</sup>, trospium 60 mg. chloride extended release capsules. In the certification, Paddock contends that U.S. Patent No. 7,410,978, listed in the Orange Book under *Sanctura XR*<sup>®</sup>, is invalid and/or not infringed by the proposed Paddock product. In June 2010, we, Endo and Supernus filed a complaint against Paddock in the U.S. District Court for the District of Delaware. The complaint alleges that Paddock s proposed product infringes U.S. Patent No. 7,410,978. In July 2010, Paddock filed an answer and counterclaims to our complaint. In July 2010, we filed a motion for leave to file an amended complaint, which Paddock did not oppose.

In July 2010, Watson filed an amended and supplemental answer and counterclaims to our complaint. In August 2010, we filed an answer to Watson s counterclaims. In August 2010, we filed an answer to Paddock s counterclaims.

In August 2010, we received an amended paragraph 4 invalidity and noninfringement Hatch-Waxman Act certification from Paddock indicating that Paddock had filed an ANDA seeking approval of a generic form of *Sanctura XR*<sup>®</sup>. In their certification, Paddock contends that U.S. Patent Nos. 7,759,359 and 7,763,635, listed in the Orange Book under *Sanctura XR*<sup>®</sup>, are invalid and/or not infringed by the proposed Paddock product. In August 2010, we received an amended paragraph 4 invalidity and noninfringement Hatch-Waxman Act certification from Watson indicating that Watson had filed an ANDA seeking approval of a generic form of *Sanctura XR*<sup>®</sup>. In their certification, Watson contends that U.S. Patent Nos. 7,759,359 and 7,763,635, listed in the Orange Book under *Sanctura XR*<sup>®</sup>, are invalid and/or not infringed by the proposed Watson product.

In September 2010, we received an amended paragraph 4 invalidity and noninfringement Hatch-Waxman Act certification from Watson indicating that Watson had filed an ANDA seeking approval of a generic form of *Sanctura XR*<sup>®</sup>. In their certification, Watson contends that U.S. Patent Nos. 7,781,448 and 7,781,449, listed in the Orange Book under *Sanctura XR*<sup>®</sup>, are invalid and/or not infringed by the proposed Watson product. In September 2010, we received an amended paragraph 4 invalidity and noninfringement Hatch-Waxman Act certification from Paddock indicating that Paddock had filed an ANDA seeking approval of a generic form of *Sanctura XR*<sup>®</sup>. In their certification, Paddock contends that U.S. Patent Nos. 7,781,448 and 7,781,449 listed in the Orange Book under *Sanctura XR*<sup>®</sup>, are invalid and/or not infringed by the proposed Paddock product. In September 2010, the court consolidated the Watson and Sandoz action with the Paddock action.

In October 2010, we, Endo and Supernus filed a complaint against Watson in the U.S. District Court for the District of Delaware. The complaint alleges that Watson s proposed product infringes U.S. Patent Nos. 7,781,448 and 7,781,449. In October 2010, Watson filed an answer and counterclaims in response to the complaint. In

October 2010, we, Endo and Supernus filed a complaint against Paddock in the U.S. District Court for the District of Delaware. The complaint alleges that Paddock s proposed product infringes U.S. Patent Nos. 7,781,448 and 7,781,449. In October 2010 and November 2010, Paddock filed answers and counterclaims in response to the complaints. In October 2010, we, Endo and Supernus filed a complaint against Watson and an amended complaint against Paddock and another defendant in the United States District Court for the District of Delaware. The complaint and amended complaint allege that the defendants proposed products infringe U.S. Patent Nos. 7,781,448 and 7,781,449. In October 2010, Paddock filed an answer to the first amended complaint and counterclaims regarding U.S. Patent No. 7,410,978.

In November 2010, Paddock filed an answer to the amended complaint and counterclaims regarding U.S. Patent Nos. 7,781,448 and 7,781,449. In November 2010, we received an amended paragraph 4 invalidity and noninfringement Hatch-Waxman Act certification from Sandoz indicating that Sandoz had filed an ANDA seeking approval of a generic form of *Sanctura XR*<sup>®</sup>, trospium 60 mg. chloride extended release capsules. In their certification, Sandoz contends that U.S. Patent Nos. 7,759,359, 7,763,635, 7,781,448, and 7,781,449, listed in the Orange Book under *Sanctura XR*<sup>®</sup>, are invalid and/or not infringed by the proposed Sandoz product.

In December 2010, we, Endo, and Supernus filed an answer to Paddock s counterclaims with respect to U.S. Patent Nos. 7,410,978, 7,781,448, and 7,781,449. In December 2010, we, Endo, and Supernus filed an answer to Watson s counterclaims with respect to U.S. Patent Nos. 7,781,448 and 7,781,449. In December 2010, we, Endo, and Supernus filed an amended answer to Paddock s counterclaims with respect to U.S. Patent Nos. 7,410,978, 7,781,448, and 7,781,449, and brought an infringement claim regarding U.S. Patent No. 7,759,359. In December 2010, we, Endo, and Supernus filed an amended answer to U.S. Patent Nos. 7,410,978, 7,781,448, and 7,781,449, and brought an infringement claim regarding U.S. Patent Nos. 7,410,978, 7,781,448 and 7,781,449, and brought an infringement claim regarding U.S. Patent Nos. 7,410,978, 7,781,448 and 7,781,449, and brought an infringement claim regarding U.S. Patent Nos. 7,410,978, 7,781,448 and 7,781,449, and brought an infringement claim regarding U.S. Patent Nos. 7,410,978, 7,781,448 and 7,781,449, and brought an infringement claim regarding U.S. Patent Nos. 7,410,978, 7,781,448 and 7,781,449, and brought an infringement claim regarding U.S. Patent Nos. 7,410,978, 7,781,448 and 7,781,449, and brought an infringement claim regarding U.S. Patent Nos. 7,410,978, 7,781,448 and 7,781,449, and brought an infringement claim regarding U.S. Patent Nos. 7,410,978, 7,781,448 and 7,781,449, and brought an infringement claim regarding U.S. Patent Nos. 7,959,359.

In January 2011, we, Endo, and Supernus filed a complaint against Sandoz in the United States District Court for the District of Delaware. The complaint alleges that Sandoz s proposed product infringes U.S. Patent Nos. 7,759,359, 7,763,635, 7,781,448, and 7,781,449. In February 2011, Sandoz filed an answer to our complaint and counterclaims. In February 2011, the court consolidated this action with the Watson, Sandoz, and Paddock actions.

#### Latisse<sup>®</sup> Patent Litigation

In July 2010, we received a paragraph 4 invalidity and noninfringement Hatch-Waxman Act certification from Apotex indicating that Apotex had filed an ANDA seeking approval of a generic form of *Latisse*<sup>®</sup>, a bimatoprost 0.3% ophthalmic solution. In the certification, Apotex contends that U.S. Patent Nos. 7,351,404 and 7,388,029, listed in the Orange Book under *Latisse*<sup>®</sup>, are invalid and/or not infringed by the proposed Apotex product. In September 2010, we and Duke University filed a complaint against Apotex in the U.S. District Court for the Middle District of North Carolina. The complaint alleges that Apotex s proposed product infringes U.S. Patent Nos. 7,351,404, 7,388,029, and 6,403,649. In November 2010, Apotex filed an answer to the complaint and counterclaims. In January 2011, we filed an answer to Apotex s counterclaims.

#### Lumigan<sup>®</sup> Patent Litigation

In March 2009, we received a paragraph 4 invalidity and noninfringement Hatch-Waxman Act certification from Barr Laboratories, Inc., or Barr, indicating that Barr had filed an ANDA seeking approval of a generic form of *Lumigan*<sup>®</sup>, a bimatoprost 0.3% ophthalmic solution. In the certification, Barr contends that U.S. Patent Nos. 5,688,819 and 6,403,649, listed in the Orange Book under *Lumigan*<sup>®</sup>, are invalid and/or not infringed by the proposed Barr product. In May 2009, we filed a complaint against Barr in the U.S. District Court for the District of Delaware. The complaint alleges that Barr s proposed product infringes U.S. Patent Nos. 5,688,819 and 6,403,649. In June 2009, Barr filed an answer to the complaint.

In December 2009, we received a paragraph 4 invalidity and noninfringement Hatch-Waxman Act certification from Sandoz, indicating that Sandoz had filed an ANDA seeking approval of a generic form of *Lumigan*<sup>®</sup>, a bimatoprost 0.3% ophthalmic solution. In the certification, Sandoz contends that U.S. Patent Nos. 5,688,819 and 6,403,649, listed in the Orange Book under *Lumigan*<sup>®</sup>, are invalid and/or not infringed by the proposed Sandoz product. In January 2010, we filed a complaint against Sandoz in the U.S. District Court for the District of Delaware. The complaint alleges that Sandoz s proposed product infringes U.S. Patent Nos. 5,688,819 and 6,403,649. In February 2010, Sandoz filed an answer and counterclaim to our complaint and we filed an answer to Sandoz s counterclaim in March 2010. In April 2010, the court consolidated the Barr and Sandoz actions and scheduled a trial date for February 1, 2011. In July 2010, we filed an amended complaint against Teva Pharmaceuticals USA, Inc., or Teva, and Teva Pharmaceutical Industries Ltd. upon belief that Barr is a wholly-owned subsidiary of Teva. In August 2010, Teva filed an answer and affirmative defenses to our amended complaint. In January 2011, the court held a bench trial and took the matter under submission.

#### Government Investigations

In September 2009, we received service of process of an Investigative Demand from the Department of Justice for the State of Oregon. The Investigative Demand requests the production of documents relating to our sales and marketing practices in connection with *Aczone*<sup>®</sup>. In December 2009, we produced documents in response to the Investigative Demand.

In June 2010, we received service of process of a Subpoena from the U.S. Securities and Exchange Commission, or SEC. The subpoena requests the production of documents relating to our affiliation with Acadia Pharmaceuticals, Inc., or Acadia, and our sale of Acadia securities. In September 2010, we produced documents responsive to the Subpoena. In January 2011, the SEC issued additional Subpoenas seeking further information, which was provided in February 2011.

In December 2010, we received service of process of a Subpoena Duces Tecum from the State of New York, Office of the Medicaid Inspector General. The subpoena requests the production of documents relating to our Eye Care Business Advisor Group, Allergan Access, and BSM Connect for Ophthalmology.

In February 2011, we received service of a Civil Investigative Demand from the United States Attorney s Office for the Southern District of New York, Civil Frauds Unit. The Investigative Demand requests the production of documents and responses to written interrogatories relating to our best prices provided to Medicaid for certain of our ophthalmic products.

In March 2008, we received service of a Subpoena Duces Tecum from the U.S. Attorney, U.S. Department of Justice, or DOJ, for the Northern District of Georgia requesting the production of documents relating to our sales and marketing practices in connection with *Botox*<sup>®</sup>. In December 2009, the DOJ for the Northern District of Georgia served us with a Supplemental Subpoena Duces Tecum requesting the production of additional documents relating to certain of our speaker bureau programs. On September 1, 2010, we announced that we reached a resolution with the DOJ, or the DOJ Settlement, regarding our alleged sales and marketing practices in connection with certain therapeutic uses of *Botox*<sup>®</sup>. In connection with the DOJ Settlement, we entered into a Federal Settlement Agreement, or Settlement Agreement, with the DOJ for the Northern District of Georgia, the Office of Inspector General of the Department of Health and Human Services, or the OIG, the TRICARE Management Activity, the U.S. Office of Personnel Management, the U.S. Department of Veterans Affairs, and the Office of Workers Compensation Programs of the U.S. Department of Labor, and the relators in the qui tam actions identified in the Settlement Agreement, pursuant to which we agreed to plead guilty to a single misdemeanor misbranding charge covering the period from 2000 through 2005 and to pay the government \$375 million, which includes a \$350 million criminal fine and \$25 million in forfeited assets. In addition, we agreed to pay \$225 million to resolve civil claims asserted by the DOJ under the civil False Claims Act. As part of the DOJ Settlement, we have entered into a five-year Corporate Integrity Agreement with the OIG. In October 2010, the U.S. District Court for the Northern District of Georgia accepted our Plea Agreement with the DOJ for the Northern District of Georgia.

#### Stockholder Derivative Litigation

In September 2010, Louisiana Municipal Police Employees Retirement System filed a stockholder derivative complaint against our current Board of Directors, or Board, which includes David E.I. Pyott, Herbert W. Boyer, Ph.D., Gavin S. Herbert, Leonard D. Schaeffer, Michael R. Gallagher, Stephen J. Ryan, M.D., Russell T. Ray, Trevor M. Jones, Ph.D., Robert A. Ingram, Louis J. Lavigne, Jr., Deborah Dunsire, M.D. and Dawn Hudson, and Allergan, Inc. in the Court of Chancery of the State of Delaware. The complaint alleges breaches of fiduciary duties relating to our alleged sales and marketing practices in connection with  $Botox^{(0)}$  and seeks to shift the costs of the DOJ Settlement to the defendants. In October 2010, the plaintiff filed an amended complaint and we and the individual defendants filed motions to dismiss.

In November 2010, we received a demand for inspection of books and records from U.F.C.W. Local 1776 & Participating Employers Pension Fund. In November 2010, the U.F.C.W. Local 1776 & Participating Employers Pension Fund filed a motion to intervene in the Louisiana Municipal Police Employees Retirement System action, which was denied by the court in January 2011.

In September 2010, Daniel Himmel filed a stockholder derivative complaint against our Board, Handel E. Evans, Ronald M. Cresswell, Louis T. Rosso, Karen R. Osar, Anthony H. Wild, and Allergan, Inc. in the U.S. District Court for the Central District of California. The complaint alleges violations of federal securities laws, breaches of fiduciary duties, waste of corporate assets, and unjust enrichment and seeks, among other things, damages, corporate governance reforms, attorneys fees, and costs.

In September 2010, Willa Rosenbloom filed a stockholder derivative complaint against our Board and Allergan, Inc. in the U.S. District Court for the Central District of California. The complaint alleges violations of federal securities law, breaches of fiduciary duties, and unjust enrichment and seeks, among other things, damages, corporate governance reforms, attorneys fees, and costs.

In September 2010, Pompano Beach Police & Firefighters Retirement System and Western Washington Laborers-Employers Pension Trust filed a stockholder derivative complaint against our Board and Allergan, Inc. in the U.S. District Court for the Central District of California. The complaint alleges violations of federal securities laws, breaches of fiduciary duties, abuse of control, gross mismanagement, and corporate waste and seeks, among other things, damages, corporate governance reforms, attorneys fees, and costs. In September 2010, plaintiffs filed a motion for consolidation with the Himmel and Rosenbloom actions, which the court granted in October 2010. In November 2010, the plaintiffs filed their consolidated complaint. In December 2010, we filed a motion to stay the consolidated action in favor of the Louisiana Municipal Police Employees Retirement System action. In December 2010, we and the individual defendants filed motions to dismiss the consolidated complaint.

In October 2010, Julie Rosenberg filed a stockholder derivative complaint against our Board and Allergan, Inc. in the Superior Court for the State of California for the County of Orange. The complaint alleges breaches of fiduciary duties and seeks, among other things, damages, attorneys fees, and costs. In December 2010, the court stayed this matter pending the decision on the motions to dismiss filed in the Louisiana Municipal Police Employees Retirement System action.

We are involved in various other lawsuits and claims arising in the ordinary course of business. These other matters are, in the opinion of management, immaterial both individually and in the aggregate with respect to our consolidated financial position, liquidity or results of operations. Because of the uncertainties related to the incurrence, amount and range of loss on any pending litigation, investigation, inquiry or claim, management is currently unable to predict the ultimate outcome of any litigation, investigation, inquiry or claim, determine whether a liability has been incurred or make an estimate of the reasonably possible liability that could result from an unfavorable outcome. We believe however, that the liability, if any, resulting from the aggregate amount of uninsured damages for any outstanding litigation, investigation or claim will not have a material adverse effect

on our consolidated financial position, liquidity or results of operations. However, an adverse ruling in a patent infringement lawsuit involving us could materially affect our ability to sell one or more of our products or could result in additional competition. In view of the unpredictable nature of such matters, we cannot provide any assurances regarding the outcome of any litigation, investigation, inquiry or claim to which we are a party or the impact on us of an adverse ruling in such matters.

Item 4. (*Removed and Reserved*).

## PART II

Item 5. *Market For Registrant s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities* The following table shows the quarterly price range of our common stock and the cash dividends declared per share of common stock during the periods listed.

	\$00000	\$00000 <b>2010</b>	\$00000	\$00000	\$00000 <b>2009</b>	\$00000
Calendar Quarter	Low	High	Div.	Low	High	Div.
First	\$ 55.25	\$ 65.79	\$ 0.05	\$ 35.41	\$ 50.89	\$ 0.05
Second	56.26	65.87	0.05	43.01	50.00	0.05
Third	57.45	67.53	0.05	44.78	58.84	0.05
Fourth	64.95	74.94	0.05	53.32	64.08	0.05

Our common stock is listed on the New York Stock Exchange and is traded under the symbol AGN.

The approximate number of stockholders of record of our common stock was 5,175 as of February 17, 2011.

On February 1, 2011, our Board of Directors declared a cash dividend of \$0.05 per share, payable March 11, 2011 to stockholders of record on February 18, 2011.

#### Securities Authorized for Issuance Under Equity Compensation Plans

The information included under Item 12 of Part III of this report, Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters, is hereby incorporated by reference into this Item 5 of Part II of this report.

#### **Issuer Purchases of Equity Securities**

The following table discloses the purchases of our equity securities during the fourth fiscal quarter of 2010.

Period	MaximumNumber Total Number of Shares Purchased(1)	Total Number Average of Shares Price Paid		Total Number of Shares Purchased as Average Part of Publicly Price Paid Announced Plans			
October 1, 2010 to October 31, 2010	266,500	\$	68.94	or Programs 266,500	or Programs(2) 14,510,369		
November 1, 2010 to November 30, 2010	733,700		69.67	733,700	16,272,230		
December 1, 2010 to December 31, 2010	255,400		68.97	255,400	16,413,178		
Total	1,255,600	\$	69.37	1,255,600	N/A		

(1) We maintain an evergreen stock repurchase program, which we first announced on September 28, 1993. Under the stock repurchase program, we may maintain up to 18.4 million repurchased shares in our treasury account at any one time. At December 31, 2010, we held approximately 2.0 million treasury shares under this program. Effective January 1, 2010, our current Rule 10b5-1 plan authorizes our

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broker to purchase our common stock traded in the open market pursuant to our evergreen stock repurchase program. The terms of the plan set forth a maximum annual limit of 4.0 million shares to be repurchased, certain quarterly maximum and minimum volume limits, and the plan is cancellable at any time in our sole discretion and in accordance with applicable insider trading laws.

(2) The share numbers reflect the maximum number of shares that may be purchased under our stock repurchase program and are as of the end of each of the respective periods.

Item 6. Selected Financial Data

## SELECTED CONSOLIDATED FINANCIAL DATA

	\$	\$000000 <b>2010</b>	Year Endec 2010 2009 2		\$000000         \$000000           led December 31,         2008         2007           except per share data)         \$1000000000000000000000000000000000000			S	\$000000 <b>2006</b>	
Summary of Operations				(	,	icept per si		, and ,		
Product net sales	\$	4,819.6	\$	4,447.6	\$	4,339.7	\$	3,879.0	\$	3,010.1
Other revenues		99.8		56.0		63.7		59.9		53.2
Total revenues		4,919.4		4,503.6		4,403.4		3,938.9		3,063.3
Operating costs and expenses:										
Cost of sales (excludes amortization of acquired intangible										
assets)		722.0		750.9		761.2		673.2		575.7
Selling, general and administrative		2,017.6		1,921.5		1,856.1		1,680.2		1,333.4
Research and development		804.6		706.0		797.9		718.1		1,055.5
Amortization of acquired intangible assets		138.0		146.3		150.9		121.3		79.6
Legal settlement		609.2								
Intangible asset impairment and related costs		369.1								
Restructuring charges		0.3		50.9		41.3		26.8		22.3
Operating income (loss)		258.6		928.0		796.0		719.3		(3.2)
Non-operating expense		(87.8)		(79.5)		(33.8)		(54.9)		(16.3)
Earnings (loss) from continuing operations before income										
taxes		170.8		848.5		762.2		664.4		(19.5)
Earnings (loss) from continuing operations		4.9		623.8		564.7		487.0		(127.0)
Loss from discontinued operations								(1.7)		
Net earnings attributable to noncontrolling interest	<b>.</b>	4.3	<b>•</b>	2.5	<b>^</b>	1.6	<b>_</b>	0.5	<b>^</b>	0.4
Net earnings (loss) attributable to Allergan, Inc.	\$	0.6	\$	621.3	\$	563.1	\$	484.8	\$	(127.4)
Basic earnings (loss) per share attributable to Allergan, Inc. stockholders:										
Continuing operations	\$	0.00	\$	2.05	\$	1.85	\$	1.59	\$	(0.43)
Discontinued operations										
Diluted earnings (loss) per share attributable to Allergan, Inc. stockholders:										
Continuing operations	\$	0.00	\$	2.03	\$	1.84	\$	1.58	\$	(0.43)
Discontinued operations								(0.01)		
Cash dividends per share	\$	0.20	\$	0.20	\$	0.20	\$	0.20	\$	0.20
Financial Position										
Current assets	\$	3,993.7	\$	3,106.3	\$	2,270.6	\$	2,124.2	\$	2,130.3
Working capital		2,465.3		2,294.7		1,573.6		1,408.5		1,472.2
Total assets		8,308.1		7,536.6		6,791.8		6,578.8		5,765.4
Long-term debt, excluding current portion										
Zong term deci, enerading earrent portion		1,534.2		1,491.3		1,570.5		1,499.4		1,491.1

In the first quarter of 2009, we adopted updates to Financial Accounting Standards Board guidance related to the accounting for convertible debt instruments that may be settled fully or partially in cash upon conversion and have retrospectively adjusted the information included in the summary of operations for the years ended December 31, 2008 and 2007 and the information included in the financial position as of December 31, 2008, 2007 and 2006. Based on an accounting policy election, we did not retrospectively adjust the information included in the summary of operations for the year ended December 31, 2006.

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### Item 7. Management s Discussion and Analysis of Financial Condition and Results of Operations

This financial review presents our operating results for each of the three years in the period ended December 31, 2010, and our financial condition at December 31, 2010. Except for the historical information contained herein, the following discussion contains forward-looking statements which are subject to known and unknown risks, uncertainties and other factors that may cause our actual results to differ materially from those expressed or implied by such forward-looking statements. We discuss such risks, uncertainties and other factors throughout this report and specifically under Item 1A of Part I of this report, Risk Factors. In addition, the following review should be read in connection with the information presented in our consolidated financial statements and the related notes to our consolidated financial statements.

#### **Critical Accounting Policies, Estimates and Assumptions**

The preparation and presentation of financial statements in conformity with accounting principles generally accepted in the United States, or GAAP, requires us to establish policies and to make estimates and assumptions that affect the amounts reported in our consolidated financial statements. In our judgment, the accounting policies, estimates and assumptions described below have the greatest potential impact on our consolidated financial statements. Accounting assumptions and estimates are inherently uncertain and actual results may differ materially from our estimates.

#### **Revenue Recognition**

We recognize revenue from product sales when goods are shipped and title and risk of loss transfer to our customers. A substantial portion of our revenue is generated by the sale of specialty pharmaceutical products (primarily eye care pharmaceuticals, skin care and urologics products) to wholesalers within the United States, and we have a policy to attempt to maintain average U.S. wholesaler inventory levels at an amount less than eight weeks of our net sales. A portion of our revenue is generated from consigned inventory of breast implants maintained at physician, hospital and clinic locations. These customers are contractually obligated to maintain a specific level of inventory and to notify us upon the use of consigned inventory. Revenue for consigned inventory is recognized at the time we are notified by the customer that the product has been used. Notification is usually through the replenishing of the inventory, and we periodically review consignment inventories to confirm the accuracy of customer reporting.

We generally offer cash discounts to customers for the early payment of receivables. Those discounts are recorded as a reduction of revenue and accounts receivable in the same period that the related sale is recorded. The amounts reserved for cash discounts were \$4.4 million and \$3.3 million at December 31, 2010 and 2009, respectively. Provisions for cash discounts deducted from consolidated sales in 2010, 2009 and 2008 were \$55.2 million, \$50.4 million and \$42.1 million, respectively.

We permit returns of product from most product lines by any class of customer if such product is returned in a timely manner, in good condition and from normal distribution channels. Return policies in certain international markets and for certain medical device products, primarily breast implants, provide for more stringent guidelines in accordance with the terms of contractual agreements with customers. Our estimates for sales returns are based upon the historical patterns of product returns matched against sales, and management s evaluation of specific factors that may increase the risk of product returns. The amount of allowances for sales returns recognized in our consolidated balance sheets at December 31, 2010 and 2009 were \$52.3 million and \$41.5 million, respectively, and are recorded in Other accrued expenses and Trade receivables, net in our consolidated balance sheets. See Note 4, Composition of Certain Financial Statement Captions in the notes to our consolidated financial statements listed under Item 15 of Part IV of this report, Exhibits and Financial Statement Schedules. Provisions for sales returns deducted from consolidated sales were \$389.3 million, \$360.6 million and \$327.7 million in 2010, 2009 and 2008, respectively. The increases in the amount of allowances for sales returns at December 31, 2010 compared to December 31, 2009 and the provisions for sales

returns in 2010 compared to 2009 are primarily due to increased sales returns related to breast implant products, principally due to increased product sales volume, and the genericization in the United States of certain eye care pharmaceutical products. The increase in the provisions for sales returns in 2009 compared to 2008 is primarily due to increased sales returns related to breast implant products, additional provisions for returns related to the genericization in the United States of certain eye care pharmaceutical products and a small increase in estimated product return rates for our other specialty pharmaceuticals products. Historical allowances for cash discounts and product returns have been consistent with the amounts reserved or accrued.

We participate in various managed care sales rebate and other incentive programs, the largest of which relates to Medicaid, Medicare and the Department of Veterans Affairs. Sales rebate and other incentive programs also include contractual volume rebate programs and chargebacks, which are contractual discounts given primarily to federal government agencies, health maintenance organizations, pharmacy benefits managers and group purchasing organizations. We also offer rebate and other incentive programs for our aesthetic products and certain therapeutic products, including Botox<sup>®</sup> Cosmetic, Juvéderm<sup>®</sup>, Latisse<sup>®</sup>, Acuvail<sup>®</sup>, Aczone<sup>®</sup> and Restasis<sup>®</sup>, and for certain other skin care products. Sales rebates and incentive accruals reduce revenue in the same period that the related sale is recorded and are included in Other accrued expenses in our consolidated balance sheets. The amounts accrued for sales rebates and other incentive programs were \$186.5 million and \$158.6 million at December 31, 2010 and 2009, respectively. Provisions for sales rebates and other incentive programs deducted from consolidated sales were \$565.3 million, \$473.8 million and \$306.2 million in 2010, 2009 and 2008, respectively. The increases in the amounts accrued at December 31, 2010 compared to December 31, 2009 and the provisions for sales rebates and other incentive programs in 2010 compared to 2009 are primarily due to an increase in activity under previously established rebate and incentive programs, principally related to our eye care pharmaceuticals, Botox<sup>®</sup> Cosmetic, skin care and facial aesthetics products, an increase in the number of incentive programs offered, additional contractual discounts to federal government agencies related to the recently enacted health care reform legislation, and increased overall product sales volume. The increase in the provisions for sales rebates and other incentive programs in 2009 compared to 2008 is primarily due to an increase in the number of incentive programs offered and an increase in activity under previously established incentive programs, principally related to our eye care pharmaceuticals, Botox® Cosmetic, skin care and facial aesthetics products. In addition, an increase in our published list prices in the United States for pharmaceutical products, which occurred for several of our products in each of 2010 and 2009, generally results in higher provisions for sales rebates and other incentive programs deducted from consolidated sales.

Our procedures for estimating amounts accrued for sales rebates and other incentive programs at the end of any period are based on available quantitative data and are supplemented by management s judgment with respect to many factors, including but not limited to, current market dynamics, changes in contract terms, changes in sales trends, an evaluation of current laws and regulations and product pricing. Quantitatively, we use historical sales, product utilization and rebate data and apply forecasting techniques in order to estimate our liability amounts. Qualitatively, management s judgment is applied to these items to modify, if appropriate, the estimated liability amounts. There are inherent risks in this process. For example, customers may not achieve assumed utilization levels; customers may misreport their utilization to us; and actual movements of the U.S. Consumer Price Index for All Urban Consumers, or CPI-U, which affect our rebate programs with U.S. federal and state government agencies, may differ from those estimated. On a quarterly basis, adjustments to our estimated liabilities for sales rebates and other incentive programs related to sales made in prior periods have not been material and have generally been less than 0.5% of consolidated product net sales. An adjustment to our estimated liabilities of 0.5% of consolidated product net sales on a quarterly basis would result in an increase or decrease to net sales and earnings before income taxes of approximately \$6.0 million to \$7.0 million. The sensitivity of our estimates can vary by program and type of customer. Additionally, there is a significant time lag between the date we determine the estimated liability and when we actually pay the liability. Due to this time lag, we record adjustments to our estimated liabilities over several periods, which can result in a net increase to earnings or a net decrease to earnings in those periods. Material differences may result in the amount of revenue we recognize from product sales if the actual amoun

We recognize license fees, royalties and reimbursement income for services provided as other revenues based on the facts and circumstances of each contractual agreement. In general, we recognize income upon the signing of a contractual agreement that grants rights to products or technology to a third party if we have no further obligation to provide products or services to the third party after entering into the contract. We defer income under contractual agreements when we have further obligations that indicate that a separate earnings process has not been completed.

#### Pensions

We sponsor various pension plans in the United States and abroad in accordance with local laws and regulations. Our U.S. pension plans account for a large majority of our aggregate pension plans net periodic benefit costs and projected benefit obligations. In connection with these plans, we use certain actuarial assumptions to determine the plans net periodic benefit costs and projected benefit obligations, the most significant of which are the expected long-term rate of return on assets and the discount rate.

Our assumption for the weighted average expected long-term rate of return on assets in our U.S. funded pension plan for determining the net periodic benefit cost is 8.25% for 2010, which is the same rate used for 2009 and 2008. Our assumptions for the weighted average expected long-term rate of return on assets in our non-U.S. funded pension plans are 5.85%, 6.03% and 6.82% for 2010, 2009 and 2008, respectively. For our U.S. funded pension plan, we determine, based upon recommendations from our pension plan s investment advisors, the expected rate of return using a building block approach that considers diversification and rebalancing for a long-term portfolio of invested assets. Our investment advisors study historical market returns and preserve long-term historical relationships between equities and fixed income in a manner consistent with the widely-accepted capital market principle that assets with higher volatility generate a greater return over the long run. They also evaluate market factors such as inflation and interest rates before long-term capital market assumptions are determined. For our non-U.S. funded pension plans, the expected rate of return was determined based on asset distribution and assumed long-term rates of return on fixed income instruments and equities. Market conditions and other factors can vary over time and could significantly affect our estimates of the weighted average expected long-term rate of return on plan assets. The expected rate of return is applied to the market-related value of plan assets. As a sensitivity measure, the effect of a 0.25% decline in our rate of return on assets assumptions for our U.S. and non-U.S. funded pension plans would increase our expected 2011 pre-tax pension benefit cost by approximately \$1.6 million.

The weighted average discount rates used to calculate our U.S. and non-U.S. pension benefit obligations at December 31, 2010 were 5.51% and 5.57%, respectively, and at December 31, 2009 were 6.04% and 6.16%, respectively. The weighted average discount rates used to calculate our U.S. and non-U.S. net periodic benefit costs for 2010 were 6.04% and 6.16%, respectively, for 2009, 6.19% and 5.71%, respectively, and for 2008, 6.25% and 5.50%, respectively. We determine the discount rate based upon a hypothetical portfolio of high quality fixed income investments with maturities that mirror the pension benefit obligations at the plans measurement date. Market conditions and other factors can vary over time and could significantly affect our estimates for the discount rates used to calculate our pension benefit obligations and net periodic benefit costs for future years. As a sensitivity measure, the effect of a 0.25% decline in the discount rate assumption for our U.S. and non-U.S. pension plans would increase our expected 2011 pre-tax pension benefit costs by approximately \$4.1 million and increase our pension plans projected benefit obligations at December 31, 2010 by approximately \$34.7 million.

#### Share-Based Compensation

We recognize compensation expense for all share-based awards made to employees and directors. The fair value of share-based awards is estimated at the grant date using the Black-Scholes option-pricing model and the portion that is ultimately expected to vest is recognized as compensation cost over the requisite service period using the straight-line single option method. The fair value of modifications to share-based awards is generally estimated using a lattice model.

The determination of fair value using the Black-Scholes and lattice option-pricing models is affected by our stock price as well as assumptions regarding a number of complex and subjective variables, including expected stock price volatility, risk-free interest rate, expected dividends and projected employee stock option exercise behaviors. We currently estimate stock price volatility based upon an equal weighting of the historical average over the expected life of the award and the average implied volatility of at-the-money options traded in the open market. We estimate employee stock option exercise behavior based on actual historical exercise activity and assumptions regarding future exercise activity of unexercised, outstanding options.

Share-based compensation expense is recognized only for those awards that are ultimately expected to vest, and we have applied an estimated forfeiture rate to unvested awards for the purpose of calculating compensation cost. These estimates will be revised in future periods if actual forfeitures differ from the estimates. Changes in forfeiture estimates impact compensation cost in the period in which the change in estimate occurs.

#### Income Taxes

The provision for income taxes is determined using an estimated annual effective tax rate, which is generally less than the U.S. federal statutory rate, primarily because of lower tax rates in certain non-U.S. jurisdictions, research and development, or R&D, tax credits available in the United States, California and other foreign jurisdictions and deductions available in the United States for domestic production activities. Our effective tax rate may be subject to fluctuations during the year as new information is obtained, which may affect the assumptions used to estimate the annual effective tax rate, including factors such as the mix of pre-tax earnings in the various tax jurisdictions in which we operate, valuation allowances against deferred tax assets, the recognition or derecognition of tax benefits related to uncertain tax positions, expected utilization of R&D tax credits and changes in or the interpretation of tax laws in jurisdictions where we conduct business. We recognize deferred tax assets and liabilities for temporary differences between the financial reporting basis and the tax basis of our assets and liabilities along with net operating loss and tax credit carryovers.

We record a valuation allowance against our deferred tax assets to reduce the net carrying value to an amount that we believe is more likely than not to be realized. When we establish or reduce the valuation allowance against our deferred tax assets, our provision for income taxes will increase or decrease, respectively, in the period such determination is made. Valuation allowances against deferred tax assets were \$4.3 million and \$4.6 million at December 31, 2010 and 2009, respectively. Changes in the valuation allowances, when they are recognized in the provision for income taxes, are included as a component of the estimated annual effective tax rate.

We have not provided for withholding and U.S. taxes for the unremitted earnings of certain non-U.S. subsidiaries because we have currently reinvested these earnings indefinitely in these foreign operations. At December 31, 2010, we had approximately \$2,109.4 million in unremitted earnings outside the United States for which withholding and U.S. taxes were not provided. Income tax expense would be incurred if these funds were remitted to the United States. It is not practicable to estimate the amount of the deferred tax liability on such unremitted earnings. Upon remittance, certain foreign countries impose withholding taxes that are then available, subject to certain limitations, for use as credits against our U.S. tax liability, if any. We annually update our estimate of unremitted earnings outside the United States after the completion of each fiscal year.

We recorded a tax benefit of \$21.4 million in the fourth quarter of 2010 in connection with the total fiscal year 2010 pre-tax charges of \$609.2 million related to the global settlement with the U.S. Department of Justice, or DOJ.

#### Acquisitions

The accounting for acquisitions requires extensive use of estimates and judgments to measure the fair value of the identifiable tangible and intangible assets acquired, including in-process research and development, and

liabilities assumed. Additionally, we must determine whether an acquired entity is considered to be a business or a set of net assets, because the excess of the purchase price over the fair value of net assets acquired can only be recognized as goodwill in a business combination.

On July 1, 2010, we completed a business combination agreement and effected a revised distribution agreement with our distributor in Turkey. We paid \$33.0 million for the termination of the original distribution agreement and purchased the commercial assets related to the selling of our products in Turkey for \$6.1 million in cash and estimated contingent consideration of \$36.7 million as of the acquisition date. On January 15, 2010, we acquired Serica Technologies, Inc., or Serica, for an aggregate purchase price of approximately \$63.7 million, net of cash acquired. On July 7, 2009, we acquired a 50.001% stockholder interest in a joint venture, Samil Allergan Ophthalmic Joint Venture Company, or Samil, for approximately \$14.8 million, net of cash acquired. We accounted for these acquisitions as business combinations. The tangible and intangible assets acquired and liabilities assumed in connection with these acquisitions were recognized based on their estimated fair values at the acquisition dates. The determination of estimated fair values requires significant estimates and assumptions including, but not limited to, determining the timing and estimated costs to complete the in-process projects, projecting regulatory approvals, estimating future cash flows and developing appropriate discount rates. We believe the estimated fair values assigned to the assets acquired and liabilities assumed are based on reasonable assumptions.

#### Impairment Evaluations for Goodwill and Purchased Intangible Assets

We evaluate goodwill for impairment on an annual basis, or more frequently if we believe indicators of impairment exist, by comparing the carrying value of each of our reporting units to their estimated fair value. We have identified two reporting units, specialty pharmaceuticals and medical devices, and currently perform our annual evaluation as of October 1 each year.

We primarily use the income approach and the market approach to valuation that include the discounted cash flow method, the guideline company method, as well as other generally accepted valuation methodologies to determine the fair value of our reporting units. Upon completion of the October 2010 annual impairment assessment, we determined that no impairment was indicated as the estimated fair value of each of the two reporting units exceeded its respective carrying value. As of December 31, 2010, we do not believe any significant indicators of impairment exist for our goodwill that would require additional analysis.

We also review purchased intangible assets for impairment when events or changes in circumstances indicate that the carrying value of our intangible assets may not be recoverable. An impairment in the carrying value of an intangible asset is recognized whenever anticipated future undiscounted cash flows from an intangible asset are estimated to be less than its carrying value.

In the third quarter of 2010, we concluded that the intangible assets and a related prepaid royalty asset associated with the *Sanctura*<sup>®</sup> franchise, or the *Sanctura*<sup>®</sup> Assets, which we acquired in connection with our 2007 acquisition of Esprit Pharma Holding Company, Inc., or Esprit, and certain subsequent licensing and commercialization transactions, had become impaired. We determined that an impairment charge was required with respect to the *Sanctura*<sup>®</sup> Assets because the estimated undiscounted future cash flows over their remaining useful life were not sufficient to recover the current carrying amount of the *Sanctura*<sup>®</sup> Assets and the carrying amount exceeded the estimated fair value of those assets due to a reduction in expected future financial performance for the *Sanctura*<sup>®</sup> franchise resulting from lower than anticipated acceptance by patients, physicians and payors. As a result, in the third quarter of 2010, we recorded an aggregate charge of \$369.1 million related to the impairment of the *Sanctura*<sup>®</sup> Assets and related costs, which includes a charge of \$343.2 million for the impairment of the *Sanctura*<sup>®</sup> intangible assets. We did not record any impairment charges in 2009. In 2008, we recorded a pre-tax impairment charge of \$5.6 million for an intangible asset related to the phase out of a collagen product.

Significant management judgment is required in the forecasts of future operating results that are used in our impairment evaluations. The estimates we have used are consistent with the plans and estimates that we use to manage our business. It is possible, however, that the plans may change and estimates used may prove to be inaccurate. If our actual results, or the plans and estimates used in future impairment analyses, are lower than the original estimates used to assess the recoverability of these assets, we could incur future impairment charges.

#### Operations

Headquartered in Irvine, California, we are a multi-specialty health care company focused on discovering, developing and commercializing innovative pharmaceuticals, biologics, medical devices and over-the-counter products 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, biologics, medical devices 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. We are a pioneer in specialty pharmaceutical research, targeting products and technologies related to specific disease areas such as chronic dry eye, glaucoma, retinal disease, psoriasis, acne, movement disorders, neuropathic pain and genitourinary diseases. Additionally, we are a leader in discovering, developing and marketing therapeutic and aesthetic biological, pharmaceutical and medical device products, including saline and silicone gel breast implants, dermal fillers and obesity intervention products. At December 31, 2010, we employed approximately 9,200 persons around the world. Our principal markets are the United States, Europe, Latin America and Asia Pacific.

## **Results of Operations**

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 dry eye, glaucoma, retinal diseases and ocular surface disease;  $Botox^{(0)}$  for certain therapeutic and aesthetic indications; skin care products for acne, psoriasis, eyelash growth and other prescription and over-the-counter skin care products; and 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<sup>®</sup> System and the Orbera Intragastric Balloon System; and facial aesthetics products. We provide global marketing strategy teams to coordinate the development and execution of a consistent marketing strategy for our products in all geographic regions that share similar distribution channels and customers.

Management evaluates our business segments and various global product portfolios on a revenue basis, which is presented below in accordance with GAAP. We also report sales performance using the non-GAAP financial measure of constant currency sales. Constant currency sales represent current period reported sales, adjusted for the translation effect of changes in average foreign exchange rates between the current period and the corresponding period in the prior year. We calculate the currency effect by comparing adjusted current period reported sales, calculated using the monthly average foreign exchange rates for the corresponding period in the prior year, to the actual current period reported sales. We routinely evaluate our net sales performance at constant currency so that sales results can be viewed without the impact of changing foreign currency exchange rates, thereby facilitating period-to-period comparisons of our sales. Generally, when the U.S. dollar either strengthens or weakens against other currencies, the growth at constant currency rates will be higher or lower, respectively, than growth reported at actual exchange rates.

The following table compares net sales by product line within each reportable segment and certain selected pharmaceutical products for the years ended December 31, 2010, 2009 and 2008:

	Year Ended E 2010	2009	0	Product N Formance		Percent Cl Total	nange in Produ Performance	
Net Sales by Product Line:								
Specialty Pharmaceuticals:								
Eye Care Pharmaceuticals	\$ 2,262.0	\$ 2,100.6	\$161.4	\$ 146.5	\$ 14.9	7.7%	7.0%	0.7%
Botox <sup>®</sup> /Neuromodulator	1,419.4	1,309.6	109.8	93.0	16.8	8.4%	7.1%	1.3%
Skin Care	229.5	208.0	21.5	21.0	0.5	10.3%	10.1%	0.2%
Urologics	62.5	65.6	(3.1)	(3.1)		(4.7)%	(4.7)%	%
Total Specialty								
Pharmaceuticals	3,973.4	3,683.8	289.6	257.4	32.2	7.9%	7.0%	0.9%
Medical Devices:								
Breast Aesthetics	319.1	287.5	31.6	31.9	(0.3)	11.0%	11.1%	(0.1)%
Obesity Intervention	243.3	258.2	(14.9)	(18.2)	3.3	(5.8)%	(7.0)%	1.2%
Facial Aesthetics	283.8	218.1	65.7	62.2	3.5	30.1%	28.5%	1.6%
Total Medical Devices	846.2	763.8	82.4	75.9	6.5	10.8%	9.9%	0.9%
Total product net sales	\$ 4,819.6	\$ 4,447.6	\$ 372.0	\$ 333.3	\$ 38.7	8.4%	7.5%	0.9%
Domestic product net sales	62.6%	65.4%						
International product net sales	37.4%	34.6%						
International product liet sales	57.470	54.0%						
Selected Product Net Sales (a):								
Alphagan <sup>®</sup> P, Alphagan <sup>®</sup> and Combigan <sup>®</sup>	\$ 401.6	\$ 414.5	\$ (12.9)	\$ (15.6)	\$ 2.7	(3.1)%	(3.8)%	0.7%
Lumigan <sup>®</sup> Franchise	526.7	456.5	70.2	71.3	(1.1)	15.4%	15.6%	(0.2)%
<i>Restasis</i> ®	620.5	522.9	97.6	96.7	0.9	18.7%	18.5%	0.2%
Sanctura <sup>®</sup> Franchise	62.5	65.6	(3.1)	(3.1)		(4.7)%	(4.7)%	%
Latisse®	81.8	73.7	8.1	7.6	0.5	11.0%	10.4%	0.6%

	Year Ended 2009	December 31, 2008 (i	,				Percent Change 1 Product Net Sales Performance Currency		
Net Sales by Product Line:									
Specialty Pharmaceuticals:									
Eye Care Pharmaceuticals	\$ 2,100.6	\$ 2,009.1	\$ 91.5	\$ 144.9	\$ (53.4)	4.6%	7.2%	(2.6)%	
<i>Botox</i> <sup>®</sup> /Neuromodulator	1,309.6	1,310.9	(1.3)	32.5	(33.8)	(0.1)%	2.5%	(2.6)%	
Skin Care	208.0	113.7	94.3	94.4	(0.1)	82.9%	83.0%	(0.1)%	
Urologics	65.6	68.6	(3.0)	(3.0)		(4.4)%	(4.4)%	%	
Total Specialty Pharmaceuticals	3,683.8	3,502.3	181.5	268.8	(87.3)	5.2%	7.7%	(2.5)%	

Medical Devices: