ALLERGAN INC
Form 10-K
March 14, 2003

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SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d)

OF THE SECURITIES EXCHANGE ACT OF 1934

For The Fiscal Year Ended December 31, 2002

Commission File No. 1-10269

Allergan, Inc.

(Exact name of Registrant as Specified in its Charter)

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

(714) 246-4500

(Registrant s telephone number)

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

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

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

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, and (2) has been subject to such filing requirements for the past 90 days. Yes þ No o.

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

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

The aggregate market value of the registrant s common equity held by non-affiliates was approximately $8,576 million on June 28, 2002, based upon the closing price on the New York Stock Exchange on such date.

Common Stock outstanding as of March 3, 2003 134,254,772 shares (including 4,533,771 shares held in treasury).

DOCUMENTS INCORPORATED BY REFERENCE

Part III incorporates certain information by reference from the registrant s proxy statement for the annual meeting of stockholders to be held on April 25, 2003, which proxy statement was filed with the Securities and Exchange Commission on March 14, 2003.

Part II, Item 5 incorporates certain information by reference from the registrant s registration statement on Form S-3, which registration statement was filed with the Securities and Exchange Commission on January 9, 2003.

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PART I

Item 1. *Business*

General Development of Our Business

Allergan, Inc. is a technology-driven, global health care company that develops and commercializes specialty pharmaceutical products for the ophthalmic, neurological, dermatological and other specialty markets. We are a pioneer in specialty pharmaceutical research, targeting products and technologies related to specific disease areas such as glaucoma, retinal disease, dry eye, psoriasis, acne, photodamage, movement disorders, metabolic disease and various types of cancer. Within these areas, we are an innovative leader in therapeutic and other prescription products, and to a limited degree, over-the-counter products that are sold in more than 100 countries around the world. With the April 2002 U.S. Food and Drug Administration (FDA) approval of our product *Botox*® Cosmetic for the temporary treatment of moderate to severe glabellar lines in adult men and women age 65 or younger, we began marketing to the consumer cosmetic market in the United States.

We were originally incorporated in California in 1948, became known as Allergan Corporation in 1950, and reincorporated in Delaware in 1977. In 1980, we were acquired by SmithKline Beecham plc (then known as SmithKline Corporation). We operated as a wholly-owned subsidiary of SmithKline from 1980 until 1989 when we again became a stand-alone public company through a spin-off distribution by SmithKline.

Our Internet website address is www.allergan.com. We make our periodic and current reports, together with amendments to these reports, available on our website, free of charge, as soon as reasonably practicable after such material is electronically filed with, or furnished to, the Securities and Exchange Commission.

On June 29, 2002, we completed the spin-off of our optical medical device business to our stockholders. The optical medical device business consisted of two businesses: our ophthalmic surgical products business, which developed, manufactured and marketed products that included artificial lenses for the eye, called intraocular lenses, and equipment for cataract and refractive eye surgery; and our contact lens care products business, which developed, manufactured and marketed a broad range of products for use with every available type of contact lens. The spin-off was effected by contributing our optical medical device business to a newly formed subsidiary, Advanced Medical Optics, Inc., and issuing a dividend of Advanced Medical Optics common stock to our stockholders. The Internal Revenue Service ruled that the transaction qualified as tax-free for Allergan and our stockholders for U.S. federal income tax purposes, with the exception of cash received for fractional shares. The common stock of Advanced Medical Optics began trading publicly on the New York Stock Exchange on July 1, 2002 under the symbol AVO. As a result of the spin-off, we continue to own and operate our specialty pharmaceutical business and Advanced Medical Optics owns and operates what was formerly our optical medical device business.

Our consolidated financial statements and related notes have been recast to reflect the financial position, results of operations and cash flows of the optical medical device business as a discontinued operation.

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Our Business

The following table sets forth, for the periods indicated, the net sales for each of our specialty pharmaceutical product lines and our long-lived assets from continuing operations:

	Year Ended December 31		
	2002	2001	2000
		(in millions)	
Eye Care Pharmaceuticals	$ 827.3	$ 753.7	$683.9
Botox®/ Neuromuscular	439.7	309.5	239.5
Skin Care Products	90.2	78.9	68.7
Other(1)	27.8		
Total Product Net Sales	$1,385.0	$1,142.1	$992.1
Sales			
Domestic	70.6%	67.0%	63.4%
International	29.4%	33.0%	36.6%
Long-Lived Assets (in millions)			
Domestic	$ 381.2	$ 354.6	$300.1
International	$ 225.2	$ 199.3	$168.9

(1) Other sales primarily include sales to Advanced Medical Optics pursuant to the manufacturing and supply agreement entered into as part of the spin-off of Advanced Medical Optics.

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

Eye Care Pharmaceutical Product Line

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

Glaucoma. The largest segment of the market for ophthalmic prescription drugs is for the treatment of glaucoma, a sight-threatening disease typically characterized by elevated intraocular pressure leading to optic nerve damage. Glaucoma is currently the world s second leading cause of blindness, and we estimate that over 60 million people worldwide have glaucoma. According to IMS Health Inc., an independent research firm, our products for the treatment of glaucoma, including *Alphagan*®, *Alphagan*® *P* and *Lumigan*®, captured approximately 16% of the worldwide glaucoma market in 2002.

Our largest selling eye care pharmaceutical products are the ophthalmic solutions *Alphagan*® (brimonidine tartrate ophthalmic solution) 0.2% and *Alphagan*® *P* (brimonidine tartrate ophthalmic solution) 0.15%, preserved with *Purite*®. *Alphagan*® and *Alphagan*® *P* lower intraocular pressure by reducing aqueous humor production and increasing uveoscleral outflow. *Alphagan*® *P* is a new and improved reformulation of *Alphagan*® containing brimonidine, *Alphagan*® s active ingredient, preserved with *Purite*®. In registration studies with the FDA, *Alphagan*® *P* demonstrated comparable efficacy to *Alphagan*® with 41% less incidence of ocular allergy. The FDA approved *Alphagan*® in September 1996 for lowering intraocular pressure in patients with open-angle glaucoma or ocular hypertension. *Alphagan*® *P* received the same FDA approval in March 2001. We sell *Alphagan*® and *Alphagan*® *P* in over 70 countries worldwide.

Alphagan® and *Alphagan*® *P* combined are the second best selling glaucoma products in the world, as measured by 2002 revenue, according to IMS Health Inc. Combined sales of *Alphagan*® and *Alphagan*® *P* represented 18% of our total consolidated sales in 2002 and 22% of our total consolidated sales in 2001. Sales of *Alphagan*® represented 23% of our total consolidated sales in 2000. In July 2002, based on the

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overwhelming acceptance of *Alphagan® P*, we discontinued the U.S. distribution of *Alphagan®*. The period of new chemical entity exclusivity in the United States for *Alphagan®* ended in September 2001. We received a 6-month exclusivity extension from the FDA for the pediatric use of *Alphagan®*, which expired in March 2002. See Item 3, Legal Proceedings, at page 16 and Note 13, Commitments and Contingencies, in the notes to the consolidated financial statements listed under Item 15(a) of Part IV of this report for further information regarding litigation involving *Alphagan®*.

In March 2001, the FDA approved *Lumigan®*, a topical treatment indicated for the reduction of elevated intraocular pressure in patients with glaucoma or ocular hypertension who are either intolerant or insufficiently responsive when treated with other intraocular pressure-lowering medications. Data suggests that *Lumigan®* lowers intraocular pressure by increasing the outflow of aqueous humor through trabecular meshwork and uveoscleral routes. *Alphagan®* and *Alphagan® P* are increasingly being prescribed by ophthalmologists as adjunctive therapy to other medications such as prostaglandins, prostamides or betablockers. For this reason, we believe that sales of *Alphagan®* and *Alphagan® P* to date have been only marginally affected by the introduction of *Lumigan®*. In March 2002, the European Commission approved *Lumigan®* through its centralized procedure. We currently sell *Lumigan®* in over 40 countries worldwide. See Item 3, Legal Proceedings, at page 16 and Note 13, Commitments and Contingencies, in the notes to the consolidated financial statements listed under Item 15(a) of Part IV of this report for further information regarding litigation involving *Lumigan®*.

In September 2001, we filed a New Drug Application with the FDA for a brimonidine and timolol combination designed to treat glaucoma. This New Drug Application remains pending.

We also market *Betagan®* ophthalmic solution, a topical betablocker used in the treatment of glaucoma, and *Propine®* ophthalmic solution, which is used alone or in combination with other drugs when initial drug therapy for glaucoma becomes inadequate. Patent protection for both products expired in the United States in 1991 and they face generic competition from several companies, including Bausch & Lomb and Alcon Laboratories, Inc. We also market our own generic version of these two products.

Ocular Surface Disease. In addition to our eye care pharmaceuticals, we market a variety of artificial tear products for various needs, under a range of brand names worldwide, led by our *Refresh®* brand. We estimate that the $500 million 2002 global lubricating tears market, according to IMS Health Inc., is growing at an approximate annual rate of 9%. With approximately 21% of this market, we believe that we are the clear global market leader, outside of Japan. In the United States, our *Refresh®* brand includes *Refresh Plus®*, the leading unit-dose tear, as measured by 2002 sales; *Refresh Tears®*, the number one multi-dose product, as measured by 2002 sales; *Refresh P.M.®* for overnight relief of dry eye; and *Refresh Liquigel®*, which combines the strength of a gel with the convenience of a liquid eye drop. In 2002, we also launched *Refresh Endura™* in the United States, a new emulsion formulation that acts on all three tear layers (lipid layer, aqueous layer and mucin layer) to provide relief of dry eye symptoms. We also market *Celluvisc®* in the United States for severe dry eye. Our other brands marketed around the world for the treatment of ocular surface disease include *Liquifilm Tears®*, *Cellufresh®* and *Lacri-Lube® S.O.P.®*, as well as *Lerin®*, a decongestant.

We also provide an eye drop for contact lens wearers called *Refresh Contacts®* to help provide comfort and protection from dryness and irritation.

In December 2002, the FDA approved *Restasis* , the first and only prescription therapy for the treatment of chronic dry eye disease. Dry eye disease is a painful and irritating condition involving abnormalities and deficiencies in the tear film initiated by a variety of causes. Moderate to severe dry eye can be associated with or can lead to inflammation and may result in serious damage to the ocular surface. The incidence increases markedly with age, after menopause in women and in people with systemic diseases such as Sjogren s syndrome and rheumatoid arthritis. Until the approval of *Restasis* , physicians used lubricating tears as a temporary measure to provide palliative relief of the debilitating symptoms of dry eye disease. We plan to launch *Restasis* early in the second quarter of 2003. In June 2001, we entered into a license, development and marketing agreement with Inspire Pharmaceuticals, Inc. Pursuant to the Inspire agreement, we obtained an exclusive license to develop and commercialize INS365 Ophthalmic worldwide, with the exception of Japan and nine other Asian countries covered by Inspire s agreement with Santen

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Pharmaceutical Co. Ltd. In return, Inspire received up to $39 million in up front and milestone payments, a co-promotion arrangement for INS365 Ophthalmic in the United States, and payments on net sales. In addition, Inspire received an option to co-promote *Restasis™* in the United States and royalties on global net sales of *Restasis™* excluding the Japan, Taiwan, Korea, Hong Kong and People s Republic of China markets. The Inspire agreement also provided for potential co-promotion by Inspire of one or more of our other marketed and future products in the United States. INS365 Ophthalmic has completed Phase III clinical trials investigating its ability to relieve the signs and symptoms of dry eye disease by rehydrating conjunctival mucosa and increasing mucin production. We believe this mechanism may be complementary to that of *Restasis* .

Ophthalmic Inflammation. Our leading ophthalmic anti-inflammatory product is *Acular*® (ketorolac 0.5%) ophthalmic solution. *Acular*® is a registered trademark of and is licensed from its developer, Syntex (U.S.A.) Inc., a business unit of Hoffmann-LaRoche Inc. *Acular*® is indicated for the relief of itch associated with seasonal allergic conjunctivitis, the inflammation of the mucus membrane that lines the inner surface of the eyelids, and for the treatment of post-operative inflammation in patients who have undergone cataract extraction. *Acular® PF* is the first, and currently remains the only unit-dose, preservative-free topical non-steroidal anti-inflammatory drug in the United States. *Acular® PF* is indicated for the reduction of ocular pain and photophobia following incisional refractive surgery and, we believe, continues to be the number one prescribed non-steroidal anti-inflammatory in the United States. See Item 3, Legal Proceedings, at page 16 and Note 13, Commitments and Contingencies, in the notes to the consolidated financial statements listed under Item 15(a) of Part IV of this report for information regarding litigation involving *Acular*®. In August 2002, Allergan filed a New Drug Application with the FDA for a reformulated ketorolac 0.4% concentration. This New Drug Application is pending.

Our product *Pred Forte*® remains the leading topical steroid worldwide, and we also market *FML® Liquifilm*® as an ophthalmic suspension in the ocular corticosteroid inflammation market. *Pred Forte*® has no patent protection and faces generic competition.

Ophthalmic Infection. Our major product in the ophthalmic anti-infective market is our *Ocuflox®/ Oflox®/ Exocin*® ophthalmic solution. According to Verispan, an independent research firm, this ophthalmic solution was the leading ocular anti-infective prescribed by ophthalmologists in the United States in 2002.

In May 2002, we filed a New Drug Application with the FDA for gatifloxacin, a new fourth generation fluoroquinolone. This New Drug Application is pending.

We also market *Blephamide*® ophthalmic suspension, a topical anti-inflammatory and anti-infective, and *Polytrim*® ophthalmic solution, a synthetic antimicrobial which treats ocular surface bacterial infections. *Blephamide*® and *Polytrim*® ophthalmic solutions no longer have patent protection and face generic competition.

Allergy. Our allergy product is *Alocril*® ophthalmic solution. *Alocril*® is indicated for the treatment of itch associated with allergic conjunctivitis. The allergy market is, by its nature, a seasonal market, peaking during the spring months. We have established a contract sales force to promote *Alocril*® to pediatricians in the United States. In December 2002, we filed a New Drug Application with the FDA for epinastine, an ocular antihistamine. This New Drug Application is pending. A Marketing Authorization Application has been filed in Europe with Sweden acting as the Reference Member State for the mutual recognition procedure in Europe.

Neuromodulator

Our neuromodulator product, *Botox*® (Botulinum Toxin Type A), is used in a wide variety of treatments which continue to expand. We believe that *Botox*® is accepted in many global regions as the standard therapy for indications ranging from therapeutic neuromuscular disorders and related pain to cosmetic facial aesthetics. We believe that there potentially are in excess of 100 therapeutic and cosmetic indications for *Botox*® based on its localized treatment effect and approximately 20 years of safety experience in large patient groups. Marketed as *Botox*®, *Botox*® Cosmetic or *Vistabel*®, depending on the indication and country of approval, we have successfully expanded the product s regulatory approvals worldwide with approvals in over

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70 countries for a broad range of indications. Sales of *Botox*® represented approximately 32%, 27% and 24% of our total consolidated sales in 2002, 2001 and 2000, respectively.

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

- the treatment of 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; and
- cervical dystonia in adults, along with the associated pain.

In certain countries outside of the United States and Japan, *Botox*® is also approved for treating blepharospasm, strabismus, cervical dystonia, hemifacial spasm, pediatric cerebral palsy, hyperhidrosis (excessive sweating) and upper limb spasticity associated with debilities occurring after a stroke. We are pursuing new approved indications for *Botox*® in the United States, Japan and Europe, including hyperhidrosis (excessive sweating), brow furrow, headache, back spasm and spasticity.

In October 2001, the European Commission granted *Botox*® a positive opinion for focal spasticity of the wrist and hand in adult post-stroke patients. Health Canada has also approved *Botox*® for the management of focal spasticity, including the treatment of upper limb spasticity associated with adult post-stroke patients. In addition, *Botox*® was granted approval for hyperhidrosis in Canada, Australia, New Zealand and the Netherlands.

Botox® *Cosmetic*. The FDA approved *Botox*® in April 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*® Cosmetic or *Vistabel*®, depending on the country of approval, this product is designed to relax wrinkle-causing muscles to smooth the deep, persistent, glabellar lines between the brow that often develop during the aging process. Health Canada had previously approved *Botox*® Cosmetic for similar use in Canada in April 2001. With the Canadian approval of *Botox*® Cosmetic, we launched our first direct-to-consumer marketing campaign aimed at building the product market. We subsequently launched a significant advertising campaign for *Botox*® Cosmetic in the United States in April 2002, including television commercials and print advertising aimed at consumers and aesthetic specialty physicians. Since its FDA approval in the United States, *Botox*® Cosmetic or *Vistabel*®, depending on the country of approval, has received approval in Australia, Switzerland and France, with France acting as the Reference Member State under the mutual recognition process in the European Union. We expect to initiate marketing of this product in other European countries in 2003. We now sponsor training of aesthetic-oriented physicians in approved countries to further expand the base of qualified physicians using *Botox*® Cosmetic or *Vistabel*®, depending on the country of approval.

Skin Care Product Line

Our skin care product line focuses on the high growth, high margin segments of the acne and psoriasis markets, particularly in the United States and Canada. Our skin care business is currently comprised of three main product lines:

- Our tazarotene products in cream and gel formulations are marketed under *Tazorac*® in the United States and Canada and as *Zorac*® elsewhere, as well as our new tazarotene cream, marketed under *Avage* ;
- *Azelex*®, an acne product; and
- our *M.D. Forte*® line of alpha hydroxy acid products.

Tazarotene Products. Since 1997, we have marketed *Tazorac*® gel in the United States for the treatment of plaque psoriasis and acne. We have marketed the cream formulation of *Tazorac*® for the treatment of psoriasis since its FDA approval in October 2000. In September 2001, we received FDA approval

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to market *Tazorac*® cream for the topical treatment of acne vulgaris. In July 2001, we entered into a co-promotion agreement for *Tazorac*® with Procter & Gamble Pharmaceuticals Inc. for the United States. Under this agreement, Procter & Gamble Pharmaceuticals markets *Tazorac*® primarily to the general practitioner market and we market *Tazorac*® to dermatologists currently covered by our in-house sales force. We have also engaged Pierre Fabre Dermatologie as our promotion partner for *Zorac*® in certain parts of Europe, the Middle East and Africa.

In October 2002, we received FDA approval for *Avage* . *Avage* is a tazarotene cream indicated for the treatment of facial fine wrinkling, mottled hypo- and hyperpigmentation (blotchy skin discoloration) and benign facial lentigines (flat patches of skin discoloration) in patients using a comprehensive skin care and sunlight avoidance program. We began marketing *Avage* in the United States in February 2003.

Azelex®. *Azelex*® cream is approved for the topical treatment of mild to moderate inflammatory acne vulgaris. We launched *Azelex*® cream in the United States in December 1995.

M.D. Forte®. We also develop and market glycolic acid-based skin care products. Our *M.D. Forte*® line of alpha hydroxy acid products are marketed to and dispensed by physicians.

Employee Relations

At December 31, 2002, we employed approximately 4,900 persons throughout the world, including approximately 2,400 in the United States. Unions do not represent any of our U.S.-based employees. We believe that our relations with our employees are, in general, very good.

International Operations

Our international sales of specialty pharmaceutical products have represented 29.4%, 33.0% and 36.6% of total sales for the years ended December 31, 2002, 2001 and 2000, respectively. Our products are sold in over 100 countries. Marketing activities are coordinated on a worldwide basis, and resident management teams provide leadership and infrastructure for customer focused rapid introduction of new products in the local markets.

Sales and Marketing

We maintain a global marketing team, as well as regional sales and marketing organizations. We also engage contract sales organizations to promote certain products. Our sales efforts and promotional activities are primarily aimed at eye care professionals, as well as neurologists, plastic surgeons and dermatologists, who use, prescribe and recommend our products. In addition, we advertise in professional journals and have an extensive direct mail program of descriptive product literature and scientific information that we provide to specialists in the ophthalmic, dermatological and movement disorder fields. We have also developed training modules and seminars to update physicians regarding evolving technology in our products. We have also utilized direct-to-consumer advertising for our *Botox*® Cosmetic and *Refresh*® products.

Our products are sold to drug wholesalers, independent and chain drug stores, pharmacies, commercial optical chains, opticians, mass merchandisers, food stores, hospitals, ambulatory surgery centers and medical practitioners, including ophthalmologists, neurologists, dermatologists, pediatricians and plastic surgeons. At December 31, 2002, we employed approximately 1,300 sales representatives throughout the world. In 2002, for the fifth year in a row, an independent survey of U.S. ophthalmologists ranked our sales force No. 1 in terms of product knowledge and service. We also utilize distributors for our products in smaller international markets.

In the United States, sales to two major wholesale customers represented 27.9% and 28.2% of our total consolidated product net sales in 2002 and 2001, respectively. In 2000, sales to three major United States wholesale customers represented 36.7% of our total consolidated product net sales. No other country, or single customer, generates over 10% of our total product net sales**.**

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Research and Development

Our global research and development efforts focus on eye care, skin care and neuromodulator products that are safe, effective and convenient and have an economic benefit. Our own research and development activities are supplemented by a commitment to identifying and obtaining new technologies through in-licensing, technological collaborations, joint ventures and acquisition efforts, including the establishment of research relationships with biotechnology companies, academic institutions and individual researchers.

At December 31, 2002, there were, in the aggregate, approximately 1,000 employees involved in our research and development efforts. Our research and development expenditures for 2002, 2001 and 2000 were $233.1 million, $227.5 million and $165.7 million, respectively, including amounts spent by us in conjunction with our 2001 acquisition of Allergan Specialty Therapeutics, Inc. We have increased our investment in research and development by over $100 million in the past five years, dedicating approximately 20% of our research investment to the discovery of new compounds. In 2002, we dedicated a new research and development facility in France, and we are continuing construction of a major new research and development facility in Irvine, California. We expect that this facility will be completed in 2004 at an aggregate cost of approximately $75 million.

Our strategy is to expand our leadership role in the science of neuromodulators, develop new potential compounds for sight-threatening diseases such as glaucoma and age-related macular degeneration and build on our strong market positions in therapeutic dry eye products and dermatology products for acne and psoriasis.

Eye Care Research and Development. Our research and development efforts for the ophthalmic pharmaceuticals business focus primarily on new therapeutic products for glaucoma, inflammation, dry eye, allergy, and anti-infective pharmaceuticals for back-of-the-eye disorders, including macular degeneration. We are working on several major research and development initiatives in the ophthalmic pharmaceutical segment, including the following:

In our glaucoma research, we are pursuing two approaches. The first is to improve upon agents for lowering intraocular pressure, and the second is to develop drugs that directly protect the optic nerve.

In the retinal disease area, we are continuing programs to treat age-related macular degeneration, the leading cause of blindness in people over the age of 50. One of our programs in this area involves identifying small molecule inhibitors of growth factor, signaling the onset of age-related macular degeneration. Another is our January 2002 collaborative effort with EntreMed, Inc. to assess the ability of *Panzem* , 2 methoxyestradiol, a small molecule angiogenic inhibitor, to block blood vessel formation in the back of the eye. Under our existing license and research agreement with Oculex Pharmaceuticals, Inc., we are also assessing the combination of *Panzem* with Oculex s novel drug delivery technology to provide localized administration of *Panzem* to the back of the eye.

We continue to pursue ocular allergy, anti-inflammatory and anti-infective products. In 2002, we filed three New Drug Applications for topical products with the FDA: topical gatifloxicin, a fourth generation fluoroquinilone anti-infective for bacterial conjunctivitis; topical epinastine, an ocular antihistamine; and a line extension for our leading non-steroidal anti-inflammatory ketorolac.

Neuromodulator Research and Development. We continue to invest heavily in the research and development of neuromodulators, primarily *Botox*®. We are focused on both expanding the approved indications for *Botox*® and pursuing new neuromodulator-based therapeutics. This includes expanding the uses for *Botox*® to include treatment for spasticity, headache, back pain, brow furrow, smooth muscle disorders and hyperhidrosis. In collaboration with the Centre for Applied Microbiology & Research, we are focused on engineering neuromodulators for the treatment of severe pain. We are also continuing our investment in the areas of biologic process development and manufacturing.

Skin Care Research and Development. Our research and development team for our skin care business is working on expanded indications and formulations for tazarotene, including an oral form of tazarotene. This oral form of tazorotene is a receptor selective retinoid agonist used for the treatment of severe psoriasis and is

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currently in Phase III development. In addition, Phase II studies for oral tazarotene in severe acne are nearly complete. The team is also working on an anti-acne approach based on enzyme inhibitors.

In November 2002, we entered into a research collaboration and license agreement with Peplin Biotech Ltd. for the right to develop and commercialize PEP005 for the topical treatment of non-melanoma skin cancer and actinic keratosis. This small molecule has shown early promise in the treatment of a wide range of human cancers, including non-melanoma and other skin cancers.

Other Areas of Research and Development. We are also working to leverage our technologies in therapeutic areas outside of our current specialties, such as the use of receptor-selective retinoid technology in therapeutic areas such as cancer, diabetes, dyslipidermia and bone disease and alpha agonists in the treatment of neuropathic pain.

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

In April 2001, we entered into agreements with Bardeen Sciences Company, LLC pursuant to which we transferred to Bardeen a portfolio of compounds and projects, agreed to perform research and development on the portfolio in exchange for a fee from Bardeen, acquired certain commercialization rights to the portfolio, and acquired an option to acquire, under certain circumstances, all of the outstanding equity of Bardeen. See Note 4, Bardeen Sciences Company, LLC, in the notes to the consolidated financial statements listed under Item 15(a) of Part IV of this report.

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

Manufacturing

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

We are vertically integrated into the production of plastic parts and produce our own bottles, tips and caps for use in the manufacture of our ophthalmic solutions. Additionally, we ferment, purify and characterize the botulinum toxin used in our product *Botox*®. With these two exceptions, we purchase all other raw materials from qualified domestic and international sources. These raw materials consist of active pharmaceutical ingredients, pharmaceutical excipients, and packaging components. Where practical, we maintain more than one supplier for each material, and we have an ongoing alternate sourcing endeavor that identifies additional sources of key raw materials. In some cases, however, most notably with active pharmaceutical ingredients, we are a niche purchaser of specialty chemicals, which are sole sourced. These sources are identified in filings with regulatory agencies, including the FDA, and cannot be changed without prior regulatory approval. In these cases, we maintain inventories of the raw material itself and precursor intermediates to mitigate the risk of interrupted supply. A lengthy interruption of the supply of one of these materials could adversely affect our ability to manufacture and supply commercial product. A small number of the raw materials required to

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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 these risks. However, a shortage, contamination or recall of these products could disrupt our ability to maintain an uninterrupted commercial supply of our finished goods.

Competition

We face strong competition in all of our markets worldwide. Numerous companies are engaged in the development, manufacture and marketing of health care products competitive with those that we manufacture. Our major eye care competitors include Alcon Laboratories, Inc., Bausch & Lomb, Pfizer, Novartis Ophthalmics and Merck & Co., Inc. These competitors have equivalent or, in most cases, greater resources than us. Our skin care business competes against a number of companies, including among others, Dermik, a division of Aventis, Galderma, a joint venture between Nestle and L Oreal, Bristol-Myers Squibb, Schering-Plough Corporation, Johnson & Johnson and Hoffman-La Roche Inc., all of which have greater resources than us. In the market for neuromodulators, we have three competitors, including Beaufour Ipsen, which sells products in Europe, Latin America, Asia, Australia and New Zealand, and Elan Corporation, PLC, which sells products in the United States and Europe. In marketing our products to health care professionals, pharmacy benefits management companies, health care maintenance organizations, and various other national and regional health care providers and managed care entities, we compete primarily on the basis of product technology, value-added services and price. We believe that we compete favorably in our product markets.

Government Regulation

Cosmetics, drugs and biologics are subject to regulation by the FDA, state agencies and, in varying degrees, by foreign health agencies. Pharmaceutical products and biologics are subject to extensive pre- and post-market regulation by the FDA, including regulations that govern the testing, manufacturing, safety, efficacy, labeling, storage, record keeping, advertising and promotion of the products under the Federal Food, Drug and Cosmetic Act and the Public Health Services Act, and by comparable agencies in a number of foreign countries. The process required by the FDA before a new drug or biologic may be marketed in the United States generally involves the following: completion of preclinical laboratory and animal testing; submission of an investigational New Drug Application, which must become effective before clinical trials may begin; and performance of adequate and well controlled human clinical trials to establish the safety and efficacy of the proposed drug or biologic for its intended use. Approval by the FDA of a New Drug Application is required prior to marketing a new drug, and approval of a Biologics License Application is required before a biologic may be legally marketed in the United States. Both New Drug Applications and Biologics License Applications must also contain extensive manufacturing information. 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.

Once approved, the FDA may withdraw product approval if compliance with pre- and post-market regulatory standards is not maintained or if problems occur after the product reaches the marketplace. In addition, the FDA may require post-marketing clinical studies 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. The FDA has broad post-market regulatory and enforcement powers, including the authority to levy fines and civil penalties, suspend or delay issuance of approvals, seize or recall products, and withdraw approvals.

The FDA imposes a number of complex regulatory requirements on entities that advertise and promote pharmaceuticals and biologics, including, but not limited to, standards and regulations for direct-to-consumer advertising, off-label promotion, industry sponsored scientific and educational activities, and promotional activities involving the Internet. The FDA has very broad enforcement authority under the Federal Food, Drug and Cosmetic Act, and failure to abide by these regulations can result in penalties, including the issuance of a Warning Letter directing the Company to correct deviations from FDA standards, a requirement that future advertising and promotional materials be pre-cleared by the FDA, and state and federal civil and criminal investigations and prosecutions.

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

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.

Internationally, the regulation of drugs is also complex. In Europe, our products are subject to extensive regulatory requirements. As in the United States, the marketing of medicinal products has for many years been subject to the granting of marketing authorizations by medicine agencies. Particular emphasis is also being placed on more sophisticated and faster procedures for reporting adverse events to the competent authorities. The European Union procedures for the authorization of medicinal products are currently being reviewed by the European Commission and proposals for improving the efficiency of operation of both the mutual recognition and centralized procedure are expected. Additionally, new rules have been introduced or are under discussion in several areas such as 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.

In Japan, where we currently sell *Botox*®, the regulatory process is equally complex. Premarketing approval and clinical studies are required, as is governmental pricing approval for pharmaceuticals. The regulatory regime for pharmaceuticals in Japan has historically been lengthy and costly, primarily because Japan required the repetition of all relevant clinical studies in Japan. In the future, the process in Japan may become more financially attractive as Japan is in the process of implementing changes to comply with the International Conference on Harmonization, an agreement among Japan, the United States and the European Union to facilitate the registration of drugs utilizing data collected outside of the country. The timeline for completion of these changes and the rules during this period of transition are not certain, and during this period registration of pharmaceutical products will remain unpredictable. However, the opportunity to realize value in Japan from our newly developed products may increase as the environment in Japan moves closer to that of the European Union and United States.

Proposals to add a specific drug benefit to the Medicare program is currently being considered in the U.S. Congress. Under some proposals, price controls could be imposed on our products. If such legislation is passed and a law is implemented, price controls could materially and adversely affect our revenues and financial condition. Price reductions have recently been mandated in several European countries, principally Germany and Italy. Certain products are also no longer eligible for reimbursement in France and Italy. Reference pricing is used in several markets around the world to reduce prices. Furthermore, parallel imports within the European Union, whereby products flow from relatively low-priced to high-priced markets, have been increasing rapidly.

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

Patents, Trademarks and Licenses

We own, or are licensed under numerous U.S. and foreign patents relating to our products, product uses and manufacturing processes. We believe that our patents and licenses are important to our business, but that with the exception of the U.S. and European patents relating to *Lumigan*®, *Acular*®, *Alphagan*® *P* and *Ocuflox*®, no one patent or license is currently of material importance in relation to our overall sales. The U.S. compound and ophthalmic use patents covering *Lumigan*® expire in 2012 (2013 in Europe); the U.S. patent

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covering the commercial formulation of *Acular*® expires in 2009 (2008 in Europe); the U.S. patent covering the commercial formulation of *Alphagan*® *P* expires in 2012 (2009 in Europe); and the U.S. compound and ophthalmic use patents covering *Ocuflox*® expire in 2004 (2003 2007 in Europe).

Our success with our products will depend, in part, on our ability to obtain, and successfully defend if challenged, patent or other proprietary protection. However, the issuance of a patent is not conclusive as to its validity or as to the enforceable scope of the claims of the patent. Accordingly, our patents may not prevent other companies from developing similar or functionally equivalent products or from successfully challenging the validity of our patents. Hence, if our patent applications are not approved or, even if approved, such patents are circumvented or not upheld in a court of law, 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 or they may be challenged or circumvented by competitors, in which case our ability to commercially exploit these products may be diminished.

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 Certain Trends and Factors Affecting Allergan and its Businesses We may be subject to intellectual property litigation and infringement claims, which could cause us to incur significant expenses or prevent us from selling our products.

We also rely on trade secrets and proprietary know-how that we seek to protect, in part, through confidentiality agreements with our partners, customers, employees and consultants. It is possible that these agreements will be breached or 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 otherwise become known or independently developed by competitors.

We may find it necessary to initiate litigation to enforce our patent rights, to protect our trade secrets or know-how or to determine the scope and validity of the proprietary rights of others. Litigation involving patents, trademarks, copyrights and proprietary technologies can often be protracted and expensive and, as with litigation generally, the outcome is inherently uncertain. See Item 3, Legal Proceedings, at page 16 and Note 13, Commitments and Contingencies, in the notes to the consolidated financial statements listed under Item 15(a) of Part IV of this report for information concerning our current patent litigation.

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.

Environmental Matters

We are subject to federal, state, local and foreign environmental laws and regulations. We believe that our operations comply in all material respects with applicable environmental laws and regulations in each country where we have a business presence. Although we continue to make capital expenditures for environmental protection, we do not anticipate any significant expenditure 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, taken as a whole, is not materially affected by seasonal factors.

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CERTAIN FACTORS AND TRENDS AFFECTING ALLERGAN AND ITS BUSINESSES

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, Section 21 of the Securities Exchange Act of 1934 and the Private Securities Litigation Reform Act of 1995. These forward-looking statements are necessarily estimates reflecting the best judgment of senior management and include comments which express our opinions about trends and factors which may impact future operating results. Disclosures which use words such as we believe, anticipate, estimate, intend, could, plan, expect and similar expressions are in identify forward-looking statements. Such statements rely on a number of assumptions concerning future events, many of which are outside of our control, and involve certain risks and uncertainties that could cause actual results to differ materially from opinions and expectations. Any such forward-looking statements, whether made in this report or elsewhere, should be considered in context with the various disclosures made by us about our businesses including, without limitation, the risk factors discussed below.

We operate in a rapidly changing environment that involves a number of risks. The following discussion highlights some of these risks and others are discussed elsewhere in this report. These and other risks could materially and adversely affect our business, financial condition, operating results or cash flows.

We operate in a highly competitive business.

The pharmaceutical industry is highly competitive. This competitive environment requires an ongoing, extensive search for technological innovation. It also requires an ability to market products effectively, including the ability to communicate the effectiveness, safety and value of products to actual and prospective customers. Our competitors often have greater resources than us. This enables them, among other things, to spread their research and development costs over a broader revenue base. In addition to product development, other competitive factors in the pharmaceutical industry include industry consolidation, product quality and price, reputation, service and access to technical information. It is possible that developments by our competitors could make our products or technologies noncompetitive or obsolete. In addition, competition from manufacturers of generic drugs is a major challenge in the United States and is growing internationally.

Prior to December 2000, we were the only manufacturer of a neuromodulator approved by the FDA, *Botox*®. Another company has now received FDA approval of a neuromodulator and we are aware of at least one other manufacturer that intends to seek approval to market a competing neuromodulator in the United States. Our sales of *Botox*® could be materially and negatively impacted by this competition or competition from other companies that might obtain FDA approval to market a neuromodulator.

In April 2002 the FDA approved *Botox*® Cosmetic for the temporary improvement in the appearance of moderate to severe glabellar lines in adult men and women age 65 or younger. *Botox*® Cosmetic is a consumer product. If we fail to anticipate, identify or to react to competitive products or if changing preferences of consumers in the cosmetic marketplace shift to other treatments for the temporary improvement in the appearance of moderate to severe glabellar lines, we may experience a decline in demand for *Botox*® Cosmetic. In addition, the popular media may produce negative reports on the efficacy, safety or side effects of *Botox*® Cosmetic, which could negatively impact consumer perceptions of the product and cause a decline in demand. We cannot assure you that consumers will continue to prefer *Botox*® Cosmetic over other treatment options, or that we can or will respond in a timely manner to changes in consumer preferences.

We could experience difficulties creating bulk toxin needed to produce Botox®.

The manufacturing process to create bulk toxin raw material necessary to produce *Botox*® is technically complex and requires significant lead-time. Any failure by us to forecast demand for, or maintain an adequate supply of, bulk toxin and finished product could result in an interruption in the supply of *Botox*® and a resulting decrease in sales of the product.

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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 claims by consumers and other third parties. We have in the past been, and continue to be, subject to various product liability claims. 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 experience material losses due to product liability claims, product recalls or corrections. Additionally, our products may cause, or may appear to cause, serious adverse side effects or potentially dangerous drug interactions if misused or improperly prescribed. These events, among others, could result in additional regulatory controls that could limit the circumstances under which our products are prescribed or 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 other alternatives to our products, even if our products are ultimately determined not to have been the primary cause of the event, thereby decreasing our sales.

Health care initiatives and other cost-containment pressures could cause us to sell our products at lower prices, resulting in less revenue to us.

Some of our products are purchased or reimbursed by state and federal government authorities, private health insurers and other organizations, such as health maintenance organizations, or HMOs, and managed care organizations, or MCOs. Third party payors increasingly challenge pharmaceutical product pricing. The trend toward managed healthcare in the United States, the growth of organizations such as HMOs and MCOs, and legislative proposals to reform healthcare and government insurance programs could significantly influence the purchase of pharmaceutical products, resulting in lower prices and/or a reduction in demand. Such cost containment measures and healthcare reform could affect our ability to sell our products. Furthermore, individual states have become increasingly aggressive in passing legislation and regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on access to certain products, importation from other countries and bulk purchasing. If these measures become law, and if these measures impose price controls or otherwise negatively impact our prices, our revenues and financial condition could be materially and adversely affected. We encounter similar regulatory and legislative issues in most other countries outside the United States.

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, gross profit or operating expenses.

We are subject to risks associated with doing business internationally.

Our business is subject to other risks generally associated with doing business internationally, including political unrest and changing economic conditions in countries where our products are sold or manufactured. We cannot assure you that we can successfully manage these risks or avoid their effects.

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

Patent protection is generally important in the pharmaceutical industry. 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 products rely on unpatented proprietary

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technology, we cannot assure you that others will not commercialize products substantially identical to such products. Generic drug manufacturers are challenging the patents covering several of our medicines. We also rely on trade secrets and proprietary know-how that we seek to protect, in part, through confidentiality agreements with partners, customers, employees and consultants. 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 or prevent us from selling our products.

Although we have a corporate policy not to infringe the valid and enforceable patents of others, we cannot assure you that our products will not infringe patents held by third parties. In such event, licenses from those third parties may not be available or may not be available on commercially attractive terms. We may have to defend, and have recently defended, against charges that we violated patents or 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 or manufacture 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, results of operations and cash flows. See Item 3, Legal Proceedings, at page 16 and Note 13, Commitments and Contingencies, in the notes to the consolidated financial statements listed under Item 15(a) of Part IV of this report for information on current patent litigation.

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

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

Our future success depends upon our ability to develop new products, and new indications for existing products, that achieve market acceptance.

Our future performance will be affected by the market acceptance of products such as *Lumigan*® and *Alphagan*® *P*, as well as FDA approval of new indications for products such as *Botox*®. We have allocated substantial resources to the development and introduction of new products and indications. New products must be continually developed, tested and manufactured and, in addition, must meet regulatory standards and receive requisite regulatory approvals in a timely manner. Products that we are currently developing may or may not receive the regulatory approvals necessary for marketing. Furthermore, the development and commercialization process is time consuming, costly and subject to numerous factors that may delay or prevent the development and commercialization of new products, including legal actions brought by our competitors. If any of our products cannot be successfully or timely commercialized, our operating results could be adversely affected. Delays or unanticipated costs in any part of the process or our inability to obtain regulatory approval for our products, including failing to maintain manufacturing facilities in compliance with all applicable regulatory requirements, could cause our operating results to suffer. We cannot assure you that new products or indications will be successfully developed, receive regulatory approval or achieve market acceptance.

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

As part of our business strategy, we plan to consider, and as appropriate, make acquisitions of technologies, products and businesses, which may result in difficulties in integrating the technologies, products and businesses acquired and/or result in significant charges to earnings that may adversely affect our stock price and financial condition. We regularly review potential acquisitions of technologies, products and businesses complementary to our business. Acquisitions typically entail many risks and could result in difficulties in integrating the operations, personnel, technologies and products of the companies acquired. If we are unable to successfully integrate our acquisitions, we may not obtain the advantages that the acquisitions were intended to create, which may adversely affect our business, results of operations, financial condition and cash flows, our ability to develop and introduce new products and the market price of our stock. In addition, 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, our products or those of our customers and the products of companies we acquire may overlap, 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.

Extensive industry regulation has had, and will continue to have, a significant impact on our business, especially our product development and manufacturing capabilities. All pharmaceutical companies, including Allergan, are subject to extensive, complex, costly and evolving regulation by the federal government, principally the FDA and to a lesser extent by the U.S. Drug Enforcement Administration, and foreign and state government agencies. The Federal Food, Drug and Cosmetic Act, the Controlled Substances Act and other domestic and foreign statutes and regulations govern or influence the testing, manufacturing, packing, labeling, storing, record keeping, safety, approval, advertising, promotion, sale and distribution of our products. Under certain of these regulations, we are subject to periodic inspection of our facilities, procedures and operations and/or the testing of our products by the FDA, the DEA and other authorities, which conduct periodic inspections to confirm that we are in compliance with all applicable regulations. In addition, the FDA conducts pre-approval and post-approval reviews and plant inspections to determine whether our systems and processes are in compliance with good manufacturing practices and other FDA regulations. The process for obtaining governmental approval to manufacture pharmaceutical products is rigorous, time-consuming and costly, and we cannot predict the extent to which we may be affected by legislative and regulatory developments. We are dependent on receiving FDA and other governmental approvals prior to manufacturing, marketing and shipping our products. Consequently, there is always a risk that the FDA or other applicable governmental authorities will not approve our products, or that the rate, timing and cost of such approvals will adversely affect our product introduction plans or results of operations.

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 are located in Irvine, California. We have three additional facilities in California, two for raw material support (both leased) and one leased administrative facility. We own one facility in Texas for manufacturing and warehousing.

Outside of the United States, we own and operate two facilities for manufacturing and warehousing in Brazil and Ireland. Other material facilities include one leased facility for administration and warehousing in Mexico; leased facilities for administration, warehousing and research and development in Japan; leased facilities for administration in Australia, Brazil, Canada, Germany, Hong Kong, Ireland, Italy, Spain and the United Kingdom; and leased facilities for administration and research and development in France.

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Item 3. ***Legal Proceedings***

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

We engaged in litigation with Pharmacia Corporation and Columbia University regarding certain patents owned or controlled by Pharmacia, which Pharmacia contended covered *Lumigan*®. On March 1, 2001, after concluding that Pharmacia planned to file a patent infringement lawsuit against us regarding *Lumigan*®, we filed a declaratory relief lawsuit in the United States District Court for the District of Delaware entitled Allergan, Inc., et al. v. Pharmacia Corporation, et al. and The Trustees of Columbia University in the City of New York. Pharmacia filed an answer to the complaint denying our allegations. Pharmacia and Columbia University also filed a counterclaim against us, alleging that we infringed the same two patents that we identified in our complaint. On November 15, 2001, we filed a pan-European (excluding the United Kingdom) declaratory relief lawsuit against Pharmacia (and related entities) in the Swedish District Court seeking a declaration applying across Europe (excluding the United Kingdom) that *Lumigan*® does not infringe a patent owned or controlled by Pharmacia. On March 13, 2002, Pharmacia responded to the Swedish declaratory proceedings by alleging, among other things, that *Lumigan*® infringed the patent at issue. On January 31, 2002, we filed an action for a declaration of non-infringement and for revocation of a Pharmacia patent related to *Lumigan*® in the High Court of Justice in the United Kingdom. On March 15, 2002, Pharmacia filed a defense in the United Kingdom denying our allegations. On March 27, 2002, Pharmacia filed a counterclaim against us in the United Kingdom action, alleging that *Lumigan*® infringed the patent at issue. We subsequently filed patent invalidity actions in the Netherlands and Sweden against the Dutch and Swedish counterparts of the same patent that was contested in the United Kingdom. In October 2002, we reached a global settlement with Pharmacia and Columbia University resolving all intellectual property disputes between them and us regarding *Lumigan*® worldwide. Under the terms of the global settlement, we paid Pharmacia $120 million in the fourth quarter of 2002 and will pay royalties on future sales of *Lumigan*® for a specified time. In November 2002, the United States District Court for the District of Delaware entered an order dismissing with prejudice the *Lumigan*® intellectual property lawsuits with Pharmacia and Columbia University that were venued in the United States. In November 2002 and early December 2002, we obtained dismissals with prejudice of the related United Kingdom, Dutch and Swedish actions.

On June 6, 2001, after receiving paragraph 4 invalidity and noninfringement Hatch-Waxman Act certifications from Apotex indicating that Apotex had filed an Abbreviated New Drug Application with the FDA for a generic form of *Acular*®, we and Syntex, the holder of the *Acular*® patent, filed a lawsuit entitled Syntex (U.S.A.) LLC and Allergan, Inc. v. Apotex, Inc., et al. in the United States District Court for the Northern District of California. On December 17, 2002, we filed a motion for partial summary judgment. On December 17, 2002, Apotex also filed a motion for summary judgment. Oral arguments on the respective motions for summary judgment were heard on March 11, 2003 and the court took the matters under submission. Trial is presently scheduled for May 27, 2003. We have also filed a separate lawsuit in Canada against Apotex similarly relating to a generic version of *Acular*®.

On December 20, 2001, a class action lawsuit entitled Citizens for Consumer Justice, et al. v. Abbott Laboratories, Inc., Allergan, Inc., et al. was filed in the United States District Court for the District of Massachusetts. The lawsuit contended that Allergan and 22 other pharmaceutical companies violated the Racketeering Influenced and Corrupt Organization Act by promulgating average wholesale prices that bear no relation to actual wholesale prices, abusing Congressional authority to formulate and publish legitimate and accurate average wholesale prices, creating artificial and inflated average wholesale prices for publication in resources used by carriers and clinicians to determine Medicare reimbursement allowances and encouraging clinicians to administer drugs with the highest average wholesale prices. A notice of related action was filed with the Judicial Panel for Multidistrict Litigation. The case was subsequently consolidated with the below-referenced Teamsters Health & Welfare Fund of Philadelphia and Vicinity v. Abbott Laboratories, Inc., Allergan, Inc., et al. class action lawsuit and related cases. A Stipulation of Voluntary Dismissal Without Prejudice as to Allergan was filed on October 28, 2002 and the court issued an order of dismissal on November 6, 2002.

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On January 9, 2002, we filed a patent infringement lawsuit in the United States District Court for the Central District of California entitled Allergan, Inc., et al. v. Alcon Laboratories, Inc., et al. and Bausch & Lomb Incorporated. We filed the complaint after Alcon and Bausch & Lomb challenged certain patents covering *Alphagan*® and after Alcon and Bausch & Lomb filed Abbreviated New Drug Applications with the FDA for a generic version of *Alphagan*®. In our complaint, we asked the court to find that the *Alphagan*® patents at issue are valid and infringed by the drug products sought to be approved in the Alcon and Bausch & Lomb Abbreviated New Drug Applications. On April 1, 2002, Alcon filed a motion for summary judgment that the court granted on May 8, 2002. Also on May 8, 2002, Bausch & Lomb filed a motion for summary judgment that the court granted on June 4, 2002. On July 12, 2002, we filed an expedited appeal with the United States Court of Appeals for the Federal Circuit seeking to overturn those rulings. On October 11, 2002, the court heard oral argument on our appeal and took the matter under submission. We are presently awaiting a ruling from the court.

On April 10, 2002, a class action lawsuit entitled Teamsters Health & Welfare Fund of Philadelphia and Vicinity v. Abbott Laboratories, Inc., Allergan, Inc., et al. was filed in the United States District Court for the District of Pennsylvania. The lawsuit contended that ten pharmaceutical companies, including Allergan, violated the Racketeering Influenced and Corrupt Organization Act by implementing fraudulent marketing and sales schemes to substantially increase and/or maintain the sales of their pharmaceutical products, which are administered directly by doctors and other medical providers, by deliberately overstating the products average wholesale prices. The case was subsequently consolidated with the above-referenced Citizens for Consumer Justice, et al. v. Abbott Laboratories, Inc., Allergan, Inc., et al. class action lawsuit and related cases. A Stipulation of Voluntary Dismissal Without Prejudice as to Allergan was filed on October 28, 2002 and the court issued an order of dismissal on November 6, 2002.

On August 29, 2002, a complaint entitled Gary F. Lyons & Associates, Inc. v. Pacific National Group, Inc., Allergan, Inc., et al. was filed in the Superior Court of the State of California for the Cou