EXHIBIT D

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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, 2004

Commission File No. 1-10269

Allergan, Inc.

(Exact name of Registrant as Specified in its Charter)

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

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

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

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

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

Indicate by check mark 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 ☑ No ☐ .

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

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

The aggregate market value of the registrant's common equity held by non-affiliates was approximately $11,819 million on June 25, 2004, based upon the closing price on the New York Stock Exchange on such date.

Common Stock outstanding as of February 25, 2005 — 134,254,772 shares (including 2,649,633 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 26, 2005, which proxy statement will be filed no later than 120 days after the close of the registrant's fiscal year ended December 31, 2004.

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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 and movement disorders. Additionally, we develop and market aesthetic-related pharmaceuticals and over-the-counter products. 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. We are also focusing research and development efforts on new therapeutic areas, including gastroenterology, neuropathic pain and genitourinary diseases.

We were originally incorporated in California in 1948 and became known as Allergan Corporation in 1950. In 1977, we reincorporated in Delaware. In 1980, we were acquired by SmithKline Beecham plc (then known as SmithKline Corporation). From 1980 through 1989, we operated as a wholly-owned subsidiary of SmithKline and in 1989 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 Internet website, free of charge, as soon as reasonably practicable after such material is electronically filed with, or furnished to, the Securities and Exchange Commission. The information on our Internet website is not incorporated by reference in this Annual Report on Form 10-K.

In June 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 and our contact lens care products business. The spin-off was effected by contributing our optical medical device business to a newly formed subsidiary, Advanced Medical Optics, Inc., or AMO, and issuing a dividend of AMO's common stock to our stockholders. Our consolidated financial statements and related notes reflect the financial position, results of operations and cash flows of the optical medical device business as a discontinued operation.

In October 2004, our board of directors approved certain restructuring activities related to the scheduled termination of our manufacturing and supply agreement with AMO. Under the manufacturing and supply agreement, which was entered into in connection with the AMO spin-off, we agreed to manufacture certain products for AMO for a period of up to three years ending in June 2005. As part of the termination of the manufacturing and supply agreement, we will eliminate certain manufacturing positions at our Westport, Ireland; Waco, Texas; and Guarulhos, Brazil manufacturing facilities. We anticipate that the pre-tax restructuring charges to be incurred in connection with the termination of the manufacturing and supply agreement will total between $24 million and $28 million and that there will be a reduction in our workforce of approximately 350 individuals.

In January 2005, our board of directors approved the initiation and implementation of a restructuring of certain activities related to our European operations. The restructuring seeks to optimize operations, improve resource allocation and create a scalable, lower cost and more efficient operating model for our European research and development and commercial activities. Specifically, the restructuring anticipates moving key European research and development and select commercial functions from our Mougins, France and other European locations to our Irvine, California, High Wycombe, U.K. and Dublin, Ireland facilities and streamlining our European commercial back office functions. Under applicable law, the proposed restructuring requires consultations and, in certain cases, negotiations with European and national works councils, other management/ labor organizations and local authorities. The restructuring steps to be implemented and their ultimate cost will depend in part on the outcome of such consultations and negotiations. We anticipate

incurring restructuring charges and charges relating to severance, relocation and one-time termination benefits, payments to public employment and training programs, implementation, transition, capital and other asset-related expenses, duplicate operating expenses and contract termination costs in connection with the restructuring. We currently estimate that the pre-tax charges and capital expenditures resulting from the restructuring will be between $50 million and $60 million. We also estimate that the restructuring will yield annual operating cost reductions of between $6 million and $9 million.

Our Business

The following table sets forth, for the periods indicated, net sales from continuing operations for each of our specialty pharmaceutical product lines, earnings (loss) from continuing operations, domestic and international sales as a percentage of total net sales and domestic and international long-lived assets:

	Year Ended December 31,		
	2004	2003	2002
		(In millions)	
Net Sales by Product Line			
Eye Care Pharmaceuticals	$1,137.1	$ 999.5	$ 827.3
Botox ®/ Neuromodulator	705.1	563.9	439.7
Skin Care Products	103.4	109.3	90.2
Other(1)	100.0	82.7	27.8
Total	$2,045.6	$1,755.4	$1,385.0
Earnings (loss) from continuing operations	$ 377.1	$ (52.5)	$ 64.0
Sales			
Domestic	69.1%	70.4%	70.6%
International	30.9%	29.6%	29.4%
Long-Lived Assets			
Domestic	$ 593.9	$ 573.8	$ 381.2
International	$ 287.1	$ 252.9	$ 225.2

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

See Note 15, "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 17% of the worldwide glaucoma market for the first nine months of 2004.

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)

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0.15%, preserved with *Purite* ®. *Alphagan* ® and *Alphagan* ® *P* lower intraocular pressure by reducing aqueous humor production and increasing uveoscleral outflow. *Alphagan* ® *P* is an improved reformulation of *Alphagan* ® containing brimonidine, *Alphagan* ®'s active ingredient, preserved with *Purite* ®. We currently market *Alphagan* ® and *Alphagan* ® *P* in over 70 countries worldwide.

Alphagan ® and *Alphagan* ® *P* combined were the third best selling glaucoma products in the world for the first nine months of 2004, according to IMS Health Inc. Combined sales of *Alphagan* ® and *Alphagan* ® *P* represented approximately 13% of our total consolidated sales in 2004, 16% of our total consolidated sales in 2003 and 18% of our total consolidated sales in 2002. In July 2002, based on the acceptance of *Alphagan* ® *P,* we discontinued the U.S. distribution of *Alphagan* ®. In May 2004, we entered into an exclusive licensing agreement with Kyorin Pharmaceutical Co., Ltd., under which Kyorin agreed to be responsible for the development and commercialization of *Alphagan* ® and *Alphagan* ® *P* in Japan's ophthalmic specialty area. Kyorin agreed to incur associated costs and provided us with an up-front payment. Kyorin also agreed to make development and commercialization milestone payments to us, as well as royalty-based payments on product sales. We agreed to work collaboratively with Kyorin on overall product strategy and management. Kyorin subsequently sub-licensed its rights under the agreement to Senju Pharmaceutical Co., Ltd. The marketing exclusivity period for *Alphagan* ® *P* expired in the U.S. in September 2004, although we have a number of patents covering the *Alphagan* ® *P* technology that extend to 2021 in the U.S. and 2009 in Europe, with corresponding patents pending in Europe. In May 2003, the first generic form of *Alphagan* ® was approved by the U.S. Food and Drug Administration, or FDA. Additionally, a generic form of *Alphagan* ® is sold in a limited number of other countries, including Canada, Mexico, India, Brazil, Colombia and Argentina. See Item 3 of Part I of this report, "Legal Proceedings" and Note 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* ®. Falcon Pharmaceuticals, Ltd., an affiliate of Alcon Laboratories, Inc., is attempting to obtain FDA approval for and to launch a brimonidine product to compete with our *Alphagan* ® *P* product. In May 2004, we filed a New Drug Application with the FDA for a new formulation of *Alphagan* ® *P.* This New Drug Application remains pending.

Lumigan ® (bimatoprost ophthalmic solution) 0.03% is a topical treatment indicated for the reduction of elevated intraocular pressure in patients with glaucoma or ocular hypertension who are either intolerant or insufficiently responsive when treated with other intraocular pressure-lowering medications. Sales of *Lumigan* ® represented approximately 11% of our total consolidated sales in 2004, 10% of our total consolidated sales in 2003 and 9% of our total consolidated sales in 2002. In March 2002, the European Commission approved *Lumigan* ® through its centralized procedure. In January 2004, the European Union's Committee for Proprietary Medicinal Products approved *Lumigan* ® as a first-line therapy for the reduction of elevated intraocular pressure in chronic open-angle glaucoma and ocular hypertension. We currently sell *Lumigan* ® in over 40 countries worldwide. In May 2004, we entered into an exclusive licensing agreement with Senju Pharmaceutical Co., Ltd., under which Senju is responsible for the development and commercialization of *Lumigan* ® in Japan's ophthalmic specialty area. Senju will incur associated costs and provided us with an up-front payment. Senju will also make development and commercialization milestone payments to us, as well as royalty-based payments on product sales. We will work collaboratively with Senju on overall product strategy and management.

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. During the fourth quarter of 2003, we received approval from Health Canada for our brimonidine and timolol combination, which is marketed as *Combigan* ™. In December 2004, we received our first European approval of *Combigan* ™ in Switzerland. In November 2003, we filed a New Drug Application with the FDA for a *Lumigan* ® and timolol combination designed to treat glaucoma or ocular hypertension. In August 2004, we announced that the FDA issued an approvable letter regarding the *Lumigan* ® and timolol combination, setting out the conditions, including additional clinical investigation, that we must meet in order to obtain final FDA approval.

Ocular Surface Disease. In December 2002, the FDA approved *Restasis*® (cyclosporine ophthalmic emulsion) 0.05%, the first and currently the only prescription therapy for the treatment of chronic dry eye

disease. We launched *Restasis*® in the United States in April 2003. Dry eye disease is a painful and irritating condition involving abnormalities and deficiencies in the tear film initiated by a variety of causes. The incidence of dry eye disease increases markedly with age, after menopause in women and in people with systemic diseases such as Sjogren's syndrome and rheumatoid arthritis. Until the approval of *Restasis*® , physicians used lubricating tears as a temporary measure to provide palliative relief of the debilitating symptoms of dry eye disease. In June 2001, we entered into a licensing, development and marketing agreement with Inspire Pharmaceuticals, Inc. under which we obtained an exclusive license to develop and commercialize Inspire's INS365 Ophthalmic in exchange for royalty payments to Inspire on sales of both *Restasis*® and, ultimately, INS365. INS365 completed Phase III clinical trials investigating its ability to relieve the signs and symptoms of dry eye disease by rehydrating conjunctival mucosa and increasing non-lacrimal tear component production. In December 2003, the FDA issued an approvable letter for INS365 and also requested additional clinical data. In February 2005, Inspire announced that INS365 failed to demonstrate statistically significant improvement as compared to a placebo for the primary endpoint of the incidence of corneal clearing. Inspire also announced that INS365 achieved improvement compared to a placebo for a number of secondary endpoints, and that Inspire intends to file a New Drug Application amendment with the FDA by the end of the second quarter of 2005.

Ophthalmic Inflammation. Our leading ophthalmic anti-inflammatory product is *Acular* ® (ketorolac ophthalmic solution) 0.5%. *Acular* ® is a registered trademark of and is licensed from its developer, Syntex (U.S.A.) Inc., a business unit of Hoffmann-LaRoche Inc. *Acular* ® is indicated for the temporary relief of itch associated with seasonal allergic conjunctivitis, the inflammation of the mucus membrane that lines the inner surface of the eyelids, and for the treatment of post-operative inflammation in patients who have undergone cataract extraction. *Acular PF* ® was the first, and currently remains the only, unit-dose, preservative-free topical non-steroidal anti-inflammatory drug in the United States. *Acular PF* ® is indicated for the reduction of ocular pain and photophobia following incisional refractive surgery. *Acular* ® is the number one prescribed non-steroidal anti-inflammatory in the United States. See Item 3 of Part I of this report, "Legal Proceedings" 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 our successful patent infringement lawsuit against Apotex, Inc., et al. confirming the validity and enforceability of our intellectual property covering *Acular* ®. Apotex, Inc. subsequently appealed that judgment and we are currently awaiting the United States Court of Appeals for the Federal Circuit's ruling on the appeal.

In June 2003, we received FDA approval of *Acular LS*® , a reformulated ketorolac 0.4% concentration, for the reduction of ocular pain, burning and stinging following corneal refractive surgery. We launched *Acular LS* ® in the United States in August 2003.

Our product *Pred Forte*® remains a leading topical steroid worldwide based on 2004 sales. *Pred Forte*® has no patent protection or marketing exclusivity and faces generic competition.

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

In March 2003, we received FDA approval of *Zymar*® (gatifloxacin ophthalmic solution) 0.3%. *Zymar*® is the first fourth-generation fluoroquinilone to enter the market for the treatment of bacterial conjunctivitis. Laboratory studies have shown that *Zymar*® kills the most common bacteria that cause eye infections as well as specific resistant bacteria. We launched *Zymar*® in the United States in April 2003. According to Verispan, an independent research firm, *Zymar*® was the number one ocular anti-infective prescribed by ophthalmologists in the United States in 2004.

Allergy. The allergy market is, by its nature, a seasonal market, peaking during the spring months. We market *Alocril*® ophthalmic solution for the treatment of itch associated with allergic conjunctivitis. Additionally, in October 2003, we received FDA approval of *Elestat* ™ (epinastine ophthalmic solution) 0.05%, for the prevention of itching associated with allergic conjunctivitis. In December 2003, we announced the execution of an agreement with Inspire Pharmaceuticals for the co-promotion of *Elestat* ™ in the United States within the ophthalmic specialty area and to allergists. Under the terms of the agreement, Inspire

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provided us with an up-front payment and we make payments to Inspire based on *Elestat* ™ net sales. In addition, the agreement reduced our existing royalty payment to Inspire for *Restasis* ®. Inspire has primary responsibility for selling and marketing activities in the United States related to *Elestat* ™. We have retained all international marketing and selling rights. We launched *Elestat* ™ in Europe under the brand names *Relestat* ® and *Purivist* ® during 2004, and Inspire launched *Elestat* ™ in the United States during 2004.

Neuromodulator

Our neuromodulator product, *Botox* ® (Botulinum Toxin Type A), is used for a wide variety of treatments which continue to expand. *Botox* ® is accepted in many global regions as the standard therapy for indications ranging from therapeutic neuromuscular disorders and related pain to cosmetic facial aesthetics. There are currently in excess of 100 therapeutic and cosmetic uses for *Botox* ® reported in medical literature. The versatility of *Botox* ® is based on its localized treatment effect and approximately 16 years of safety experience in large patient groups. Marketed as *Botox* ®, *Botox* ® Cosmetic, *Vistabel* ® or *Vistabex* ®, depending on the indication and country of approval, the product is currently approved in over 70 countries for a broad range of indications. Sales of *Botox* ® represented approximately 34%, 32% and 32% of our total consolidated sales in 2004, 2003 and 2002, respectively.

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

- blepharospasm, the uncontrollable contraction of the eyelid muscles which can force the eye closed and result in functional blindness;
- strabismus, or misalignment of the eyes, in people 12 years of age and over;
- cervical dystonia, or sustained contractions or spasms of muscles in the shoulders or neck in adults, along with the associated pain; and
- severe primary axillary hyperhidrosis (underarm sweating) that is inadequately managed with topical agents.

In many countries outside of the United States and Japan, *Botox* ® is also approved for treating blepharospasm, strabismus, cervical dystonia, hemifacial spasm, pediatric cerebral palsy, hyperhidrosis and post-stroke focal spasticity. We are currently pursuing new indication approvals for *Botox* ® in the United States, Japan and Europe, including headache, post-stroke focal spasticity and overactive bladder.

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* ®, *Botox* ® Cosmetic, *Vistabel* ® or *Vistabex* ®, depending on the country of approval, this product is designed to relax wrinkle-causing muscles to smooth the deep, persistent, glabellar lines between the brow that often develop during the aging process. Health Canada approved *Botox* ® Cosmetic for similar use in Canada in April 2001. In 2004, we continued our previously launched direct-to-consumer marketing campaigns in Canada and the United States. These campaigns included television commercials and print advertising aimed at consumers and aesthetic specialty physicians. Currently, over 30 countries have approved the glabellar line indication for *Botox* ®, *Botox* ® Cosmetic, *Vistabel* ® or *Vistabex* ®, including Australia, Brazil, Canada, Denmark, France, Israel, Italy, Mexico, Norway, Poland, Portugal, Spain, Sweden, and Switzerland. In January 2005, we received a positive opinion from the European Union by way of the Mutual Recognition Process for *Vistabel* ®. The positive opinion was received in all twelve concerned member states in which we filed, including, among others, Austria, Hungary, Greece, Belgium and Finland. We now sponsor training of aesthetic specialty physicians in approved countries to further expand the base of qualified physicians using *Botox* ® , *Botox* ® Cosmetic, *Vistabel* ® or *Vistabex* ®.

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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.

Tazarotene Products. We market *Tazorac* ® gel in the United States for the treatment of plaque psoriasis, a chronic skin disease characterized by dry red patches, and acne. We also market the cream formulation of *Tazorac* ® in the United States for the treatment of psoriasis and the topical treatment of acne. Under a co-promotion agreement for *Tazorac* ® in the United States, PediaMed Pharmaceuticals, Inc. markets *Tazorac* ® to the pediatric medical community and Proctor & Gamble markets *Tazorac* ® to general practitioners. We market *Tazorac* ® to dermatologists with 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 of *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 launched *Avage* ® in the United States in January 2003.

In November 2003, we filed a New Drug Application with the FDA for oral tazarotene for the treatment of moderate to very severe psoriasis. In July 2004, the FDA Joint Dermatologic & Opthalmic Drugs and Drug Safety & Risk Management Advisory Committee recommended against approval of this New Drug Application, and in September 2004, the FDA issued a non-approvable letter. The FDA listed three non-approvability issues for oral tazarotene for the treatment of moderate to very severe psoriasis: (1) the development of an acceptable risk management program; (2) completion of a non-inferiority study in severe psoriasis; and (3) satisfaction of an FDA deficiency letter regarding the manufacture of the oral tazarotene capsules. We intend to continue working with the FDA toward our goal of bringing oral tazarotene to patients suffering from psoriasis.

In May 2004, we transferred certain rights to our pre-clinical programs and broad research portfolio in retinoid and rexinoid nuclear receptor compounds to Concurrent Pharmaceuticals, Inc., a privately held biopharmaceutical company. The clinical assets and compounds subject to the transaction included near-clinical compounds and were primarily derived from our retinoid program. The transaction was designed to provide Concurrent with a portfolio of development compounds and near-clinical candidates that would comprise a discovery engine with the potential to create a pipeline of product leads and follow-on programs. Under the terms of the transaction, we received equity in Concurrent, the right to designate one person to serve on Concurrent's board of directors, as well as the right to receive future milestone and royalty payments. As part of the transaction, our retinoid receptor research team joined Concurrent.

In January 2005, we launched *Prevage* ™ antioxidant cream, the first and only clinically tested antioxidant that not only reduces the appearance of fine lines and wrinkles, but also provides protection against environmental factors including sun damage, air pollution and cigarette smoke. Representing the next generation of antioxidants, *Prevage* ™ is a novel cosmeceutical containing 1% idebenone — a revolutionary, potent and effective new antioxidant. *Prevage* ™ is marketed to physicians.

Azelex® . *Azelex* ® cream is approved by the FDA for the topical treatment of mild to moderate inflammatory acne vulgaris. We market *Azelex* ® cream primarily in the United States.

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 physicians.

Finacea ®. In 2003 we entered into a collaboration with Intendis, Inc. (formerly known as Berlex, Inc.) to jointly promote Intendis' topical rosacea treatment, *Finacea* ® (azelaic acid gel 15%). *Finacea* ® is the first new therapeutic class option to be approved by the FDA for the treatment of rosacea in more than a decade and has rapidly gained a leading position in the market.

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Employee Relations

At December 31, 2004, we employed approximately 5,030 persons throughout the world, including approximately 2,490 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.

International Operations

Our international sales of specialty pharmaceutical products have represented 30.9%, 29.6% and 29.4% of total sales for the years ended December 31, 2004, 2003 and 2002, 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, neurologists, plastic surgeons and dermatologists who use, prescribe and recommend our products. 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 developed training modules and seminars to update physicians regarding evolving technology in our products. In 2004, we also utilized direct-to-consumer advertising for our *Botox* ® Cosmetic and *Restasis* ® products.

Our products are sold to drug wholesalers, independent and chain drug stores, pharmacies, commercial optical chains, opticians, mass merchandisers, food stores, hospitals, ambulatory surgery centers and medical practitioners, including ophthalmologists, neurologists, dermatologists, pediatricians and plastic surgeons. As of December 31, 2004, we employed approximately 1,400 sales representatives throughout the world. We also utilize distributors for our products in smaller international markets.

U.S. sales, including manufacturing operations, represented 69.1%, 70.4% and 70.6% of our consolidated product net sales in 2004, 2003 and 2002, respectively. Sales to Cardinal Healthcare for the years ended December 31, 2004, 2003 and 2002 were 14.1%, 14.0% and 14.8%, respectively, of our total consolidated product net sales. Sales to McKesson Drug Company for the years ended December 31, 2004, 2003 and 2002 were 13.0%, 14.2% and 13.3%, respectively, of our total consolidated product net sales. No other country, or single customer, generates over 10% of our total product net sales.

Research and Development

Our global research and development efforts currently focus on eye care, skin care, neuromodulators, and neurology. We also have development programs in genitourinary diseases and gastroenterology. We have a fully integrated pharmaceutical 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, 2004, we had approximately 1,030 employees involved in our research and development efforts. Our research and development expenditures for 2004, 2003 and 2002 were approximately $345.6 million, $763.5 million and $233.1 million, respectively, including expenditures on in-process research and development in connection with our 2003 acquisitions of Bardeen Sciences Company, LLC and Oculex Pharmaceuticals, Inc. Excluding in-process research and development expenditures, we have increased our annual investment in research and development by over $200 million in the past five years, dedicating approximately 20% of our investment in research and development to the discovery of new compounds. In 2004, we completed construction of a new $75 million research and development facility in Irvine, California, which will provide us with approximately 175,000 square feet of additional laboratory space. In 2004, we began

construction on a new biologics facility on our Irvine, California campus. We expect that this facility will be completed in 2005 at an aggregate cost of approximately $50 million.

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

Eye Care Research and Development. Our research and development efforts for the ophthalmic pharmaceuticals business focus primarily on new therapeutic products for retinal disease, glaucoma, and dry eye. As part of our focus on diseases of the retina, we acquired Oculex Pharmaceuticals, Inc. in 2003. With this acquisition, we obtained a novel drug delivery technology for use with compounds to treat diseases, including macular edema and age-related macular degeneration. We have subsequently begun Phase III studies for macular edema associated with diabetes and retinal vein occlusion. In April 2004, we announced that we were also selected as a partner to supply our novel ophthalmic formulation of triamcinolone for two National Eye Institute-sponsored clinical trials on macular edema associated with diabetic retinopathy and retinal vein occlusion. Under the terms of the clinical trial agreement, we are responsible for all costs associated with drug development, manufacturing, pharmacokinetic studies, and regulatory aspects of the trials. In addition, we will pay a fee to the study coordinating centers for the conduct of the trials.

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 approved uses for *Botox* ® to include treatment for spasticity, headache, brow furrow and urologic conditions including overactive bladder. In collaboration with the United Kingdom's Health Protection Agency, formerly known as 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 expanding indications and formulations for tazarotene. As mentioned above, we filed a New Drug Application with the FDA in November 2003 for oral tazarotene for the treatment of moderate to very severe psoriasis. In July 2004, the FDA Joint Dermatologic & Opthalmic Drugs and Drug Safety & Risk Management Advisory Committee recommended against approval of this New Drug Application, and in September 2004, the FDA issued a non-approvable letter. The FDA listed three non-approvability issues for oral tazarotene for the treatment of moderate to very severe psoriasis: (1) the development of an acceptable risk management program; (2) completion of a non-inferiority study in severe psoriasis; and (3) satisfaction of an FDA deficiency letter regarding the manufacture of the oral tazarotene capsules. We intend to continue working with the FDA toward our goal of bringing oral tazarotene to patients suffering from psoriasis.

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. In June 2004, we filed Investigational New Drug Applications with the FDA for a topical formulation of PEP005 for the treatment of actinic keratosis, a pre-cancerous skin condition, and for basal cell carcinoma, the most common form of non-melanoma skin cancer. In October 2004, we mutually agreed with Peplin to discontinue our collaboration.

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 alpha agonists for the treatment of neuropathic pain. Additionally, we are developing a novel proton pump inhibitor designed to reduce excess stomach acid secretion. In support of these two programs, we filed Investigational New Drug Applications with the FDA for a proton pump inhibitor pro drug for the treatment of gastrointestinal disease in June 2004 and for an alpha adrenergic agonist for the treatment of neuropathic pain in September 2004. These Investigational New Drug Applications remain pending.

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

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

Manufacturing

We manufacture the majority of our commercial products in our own plants located in 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 manufacture a small number of commercial products for us. However, the revenues from these products are not material to our operating results.

We are vertically integrated into the production of plastic parts and produce our own bottles, tips and caps for use in the manufacture of our ophthalmic solutions. Additionally, we ferment, purify and characterize the botulinum toxin used in our product *Botox* ®. With these two exceptions, we purchase all other 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 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.

Competition

We face significant 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. This enables them, among other things, to 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 agencies. Our skin care business competes against a number of companies, including among others, Dermik, a division of Sanofi-Aventis, Galderma, a joint venture between Nestle and L'Oreal, Medicis, Bristol-Myers Squibb, Schering-Plough Corporation and Johnson & Johnson, most of which have greater resources than us. With respect to neuromodulators, until December 2000, *Botox* ® was the only neuromodulator approved by the FDA. At that time, the FDA approved *Myobloc* ®, a neuromodulator formerly marketed by Elan Pharmaceuti-

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cals and now marketed by Solstice Neurosciences Inc. We believe that Beaufour Ipsen Ltd. intends to seek FDA approval of its *Dysport* ® neuromodulator for certain therapeutic indications, and that Beaufour Ipsen's marketing partner, Inamed Corporation, intends to seek FDA approval of *Dysport* ®/ *Reloxin* ® for cosmetic indications. Beaufour Ipsen has marketed *Dysport* ® in Europe since 1991, prior to our European commercialization of *Botox* ® in 1992. Also, Mentor Corporation has announced its intention to develop and seek regulatory approval to market a competing neuromodulator in the United States. In addition, we are aware of competing neuromodulators currently being developed and commercialized in Asia, Europe, South America and other markets. A Chinese entity received approval to market a botulinum toxin in China in 1997, and we believe that it has launched or is planning to launch its botulinum toxin product in other lightly regulated markets in Asia, South America and Central America. These lightly regulated markets may not require adherence to the FDA's current good manufacturing practices, or cGMPs, the European Medical Evaluation Agency or other regulatory agencies in countries that are members of the Organization for Economic Cooperation and Development, and companies operating in these markets may be able to produce products at a lower cost than we can. In addition, Merz Pharmaceuticals is seeking German regulatory approval for a botulinum toxin currently expected to be launched during the second half of 2005, and a Korean company is developing a botulinum toxin that received exportation approval from Korean authorities in early 2005 and that is expected to be launched in Korea during 2005.

In addition, competition from generic drug manufacturers is a major challenge in the United States and is growing internationally. 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 quality, product technology, price, reputation and access to technical information. 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 with respect to drugs and the Public Health Services Act with respect to biologics, and by comparable agencies in a number of foreign countries. Failure to comply with applicable FDA or other requirements may result in civil or criminal penalties, recall or seizure of products, partial or total suspension of production or withdrawal of a product from the market.

The process required by the FDA before a new drug or biologic may be marketed in the United States generally involves the following: completion of preclinical laboratory and animal testing; submission of an Investigational New Drug Application, which must become effective before clinical trials may begin; and performance of adequate and well controlled human clinical trials to establish the safety and efficacy of the proposed drug or biologic for its intended use. Clinical trials are typically conducted in three sequential phases, which may overlap, and must satisfy extensive Good Clinical Practice regulations and regulations for informed consent. Approval by the FDA of a New Drug Application, or NDA, is required prior to marketing a new drug, and approval of a Biologics License Application, or BLA, is required before a biologic may be legally marketed in the United States. To satisfy the criteria for approval, an NDA or BLA must demonstrate the safety and effectiveness of the product based on results of product development, preclinical studies and the three phases of clinical trials. Both NDAs and BLAs must also contain extensive manufacturing information, and the applicant must pass an FDA pre-approval inspection of the manufacturing facilities at which the drug or biologic is produced to assess compliance with the FDA's current good manufacturing practices, or 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.

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Once approved, the FDA may withdraw product approval if compliance with pre- and post-market regulatory standards is not maintained or if safety problems occur after the product reaches the marketplace. In addition, the FDA may require post-marketing clinical studies and surveillance programs to monitor the effect of approved products. The FDA may limit further marketing of the product based on the results of these post-market studies and programs. Drugs and biologics may be marketed only for the approved indications and in accordance with the provisions of the approved label. Further, any modifications to the drug or biologic, including changes in indications, labeling, or manufacturing processes or facilities, may require the submission of a new or supplemental NDA or BLA, which may require that we develop additional data or conduct additional preclinical studies and clinical trials.

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

The FDA imposes a number of complex regulatory requirements on entities that advertise and promote pharmaceuticals and biologics, including, but not limited to, standards and regulations for direct-to-consumer advertising, off-label promotion, industry sponsored scientific and educational activities, and promotional activities involving the Internet. A manufacturer can make only those claims relating to safety and efficacy that are approved by the FDA. The FDA has very broad enforcement authority under the 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 us to correct deviations from FDA standards, a requirement that future advertising and promotional materials be pre-cleared by the FDA, and state and federal civil and criminal investigations and prosecutions. Physicians may prescribe legally available drugs and biologics for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. Such off-label uses are common across medical specialties. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, impose stringent restrictions on manufacturers' communications regarding off-label use.

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

Internationally, the regulation of drugs is also complex. In Europe, our products are subject to extensive regulatory requirements. As in the United States, the marketing of medicinal products has for many years been subject to the granting of marketing authorizations by medicine agencies. Particular emphasis is also being placed on more sophisticated and faster procedures for reporting adverse events to the competent authorities. The European Union procedures for the authorization of medicinal products were amended in May 2004 and are due to be implemented by October 2005. The new procedures are intended to improve the efficiency of operation of both the mutual recognition and centralized procedures. Additionally, new rules have been introduced or are under discussion in several areas, including the harmonization of clinical research laws and the law relating to orphan drugs and orphan indications. Outside the United States, reimbursement pricing is typically regulated by government agencies.

Among other countries, we currently sell *Botox* ® in Japan, where the regulatory process is at least as equally complex as in the U.S. Pre-marketing approval and clinical studies are required, as is negotiated

governmental pricing 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. 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 transitional period are not certain. During this transitional period, registration of pharmaceutical products will remain unpredictable.

The total cost of providing health care services has been and will continue to be subject to review by governmental agencies and legislative bodies in the major world markets, including the United States, which are faced with significant pressure to lower health care costs. The Medicare Prescription Drug Modernization Act of 2003 imposed certain reimbursement restrictions on our products in the United States. These reimbursement restrictions or other price reductions or controls could materially and adversely affect our revenues and financial condition. Additionally, price reductions and rebates have recently been mandated in several European countries, principally Germany, Italy, Spain and the United Kingdom. Certain products are also no longer eligible for reimbursement in France, Italy and Germany. Reference pricing is used in several markets around the world to reduce prices. Furthermore, parallel trade within the European Union, whereby products flow from relatively low-priced to high-priced markets, has been increasing.

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

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* ® and *Alphagan* ® *P*, 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* ® currently expire in 2012. An application is pending with the U.S. Patent and Trademark Office for a patent term extension for *Lumigan* ®. The European patent covering *Lumigan* ® expires in various countries between 2013 and 2017. The U.S. patent covering the commercial formulation of *Acular* ® expires in 2009; and in 2008 in Europe. The U.S. patents covering the commercial formulation of *Alphagan* ® *P* expire in 2012 and 2021; and in 2009 in Europe, with corresponding patents pending.

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 legal proceeding, 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 Factors and Trends Affecting Allergan and its Businesses — 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."

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

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 that express our 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" and similar expressions are intended to 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 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 of the various disclosures made by us about our businesses including, without limitation,

EXHIBIT E

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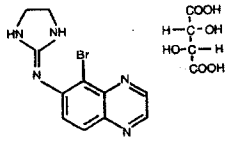
PHARMA.

BRIMONIDINE TARTRATE

ophthalmic solution, 0.2%
sterile

DESCRIPTION

Brimonidine tartrate ophthalmic solution 0.2% is a relatively selective alpha-2 adrenergic agonist for ophthalmic use. The chemical name of brimonidine tartrate is 5-bromo-6-(2-imidazolidinylideneamino) quinoxaline L-tartrate. It has a molecular weight of 442.24 as the tartrate salt and is soluble in water (5.6 mg/mL) at pH 6.5. The structural formula is:



Formula: $C_{11}H_{10}BrN_5 \cdot C_4H_6O_6$

CAS Number 59803-98-4

In solution, Brimonidine tartrate ophthalmic solution 0.2% has a clear, greenish-yellow color. It has an osmolality of 280 - 330 mOsm/kg and a pH of 5.6 - 6.6

Each mL of Brimonidine tartrate ophthalmic solution contains: **Active ingredient:** brimonidine tartrate 0.2% (2 mg/mL). **Preservative:** benzalkonium chloride (0.05 mg). **Inactives:** citric acid; polyvinyl alcohol; sodium chloride; sodium citrate; and purified water. Hydrochloric acid and/or sodium hydroxide may be added to adjust pH.

CLINICAL PHARMACOLOGY

Mechanism of action: Brimonidine tartrate ophthalmic solution is an alpha adrenergic receptor agonist. It has a peak ocular hypotensive effect occurring at two hours post-dosing. Fluorophotometric studies in animals and humans suggest that brimonidine tartrate has a dual mechanism of action by reducing aqueous humor production and increasing uveoscleral outflow.

Pharmacokinetics: After ocular administration of a 0.2% solution, plasma concentrations peaked within 1 to 4 hours and declined with a systemic half-life of approximately 3 hours. In humans, systemic metabolism of brimonidine is extensive. It is metabolized primarily by the liver. Urinary excretion is the major route of elimination of the drug and its metabolites. Approximately 87% of an orally-administered radioactive dose was eliminated within 120 hours, with 74% found in the urine.

Clinical Evaluations: Elevated IOP presents a major risk factor in glaucomatous field loss. The higher the level of IOP, the greater the likelihood of optic nerve damage and visual field loss. Brimonidine tartrate has the action of lowering intraocular pressure with minimal effect on cardiovascular and pulmonary parameters.

In comparative clinical studies with timolol 0.5%, lasting up to one year, the IOP lowering effect of Brimonidine tartrate ophthalmic solution was approximately 4-6 mm Hg compared with approximately 6 mm Hg for timolol. In these studies, both patient groups were dosed BID; however, due to the duration of action of Brimonidine tartrate ophthalmic solution, it is recommended that Brimonidine tartrate ophthalmic solution be dosed TID. Eight percent of subjects were discontinued from studies due to inadequately controlled intraocular pressure, which in 30% of these patients occurred during the first month of therapy. Approximately 20% were discontinued due to adverse experiences.

INDICATIONS AND USAGE

Brimonidine tartrate ophthalmic solution is indicated for lowering intraocular pressure in patients with open-angle glaucoma or ocular hypertension. The IOP lowering efficacy of Brimonidine tartrate ophthalmic solution diminishes over time in some patients. This loss of effect appears with a variable time of onset in each patient and should be closely monitored.

CONTRAINDICATIONS

Brimonidine tartrate ophthalmic solution is contraindicated in patients with hypersensitivity to brimonidine tartrate or any component of this medication. It is also contraindicated in patients receiving monoamine oxidase (MAO) inhibitor therapy.

PRECAUTIONS

General: Although Brimonidine tartrate ophthalmic solution had minimal effect on blood pressure of patients in clinical studies, caution should be exercised in treating patients with severe cardiovascular disease.

Brimonidine tartrate ophthalmic solution has not been studied in patients with hepatic or renal impairment; caution should be used in treating such patients.

Brimonidine tartrate ophthalmic solution should be used with caution in patients with depression, cerebral or coronary insufficiency, Raynaud's phenomenon, orthostatic hypotension or thromboangiitis obliterans.

During the studies there was a loss of effect in some patients. The IOP-lowering efficacy observed with Brimonidine tartrate ophthalmic solution during the first month of therapy may not always reflect the long-term level of IOP reduction. Patients prescribed IOP-lowering medication should be routinely monitored for IOP.

Information for Patients: The preservative in Brimonidine tartrate ophthalmic solution, benzalkonium chloride, may be absorbed by soft contact lenses. Patients wearing soft contact lenses should be instructed to wait at least 15 minutes after instilling Brimonidine tartrate ophthalmic solution to insert soft contact lenses.

As with other drugs in this class, Brimonidine tartrate ophthalmic solution may cause fatigue and/or drowsiness in some patients. Patients who engage in hazardous activities should be cautioned of the potential for a decrease in mental alertness.

Drug Interactions: Although specific drug interaction studies have not been conducted with Brimonidine tartrate ophthalmic solution, the possibility of an additive or potentiating effect with

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CNS depressants (alcohol, barbiturates, opiates, sedatives, or anesthetics) should be considered. Alpha-agonists, as a class, may reduce pulse and blood pressure. Caution in using concomitant drugs such as beta-blockers (ophthalmic and systemic), antihypertensives and/or cardiac glycosides is advised.

Tricyclic antidepressants have been reported to blunt the hypotensive effect of systemic clonidine. It is not known whether the concurrent use of these agents with Brimonidine tartrate ophthalmic solution in humans can lead to resulting interference with the IOP lowering effect. No data on the level of circulating catecholamines after Brimonidine tartrate ophthalmic solution instillation are available. Caution, however, is advised in patients taking tricyclic antidepressants which can affect the metabolism and uptake of circulating amines.

Carcinogenesis, mutagenesis, impairment of fertility: No compound-related carcinogenic effects were observed in either mice or rats following a 21 month and 24-month study, respectively. In these studies, dietary administration of brimonidine tartrate at doses up to 2.5 mg/kg/day in mice and 1.0 mg/kg/day in rats achieved ~77 and 118 times, respectively, the plasma drug concentration estimated in humans treated with one drop Brimonidine tartrate ophthalmic solution into both eyes 3 times per day.

Brimonidine tartrate was not mutagenic or cytogenic in a series of *in vitro* and *in vivo* studies including the Ames test, chromosomal aberation assay in Chinese Hamster Ovary (CHO) cells, a host-mediated assay and cytogenic studies in mice, and dominant lethal assay.

Reproductive studies performed in rats with oral doses of 0.66 mg base/kg revealed no evidence of impaired fertility due to Brimonidine tartrate ophthalmic solution.

Pregnancy: Teratogenic Effects: Pregnancy Category B. Reproductive studies performed in rats with oral doses of 0.66 mg base/kg revealed no evidence of harm to the fetus due to Brimonidine tartrate ophthalmic solution. Dosing at this level produced 100 times the plasma drug concentration level seen in humans following multiple ophthalmic doses.

There are no adequate and well-controlled studies in pregnant women. In animal studies, brimonidine crossed the placenta and entered into the fetal circulation to a limited extent. Brimonidine tartrate ophthalmic solution should be used during pregnancy only if the potential benefit to the mother justifies the potential risk to the fetus.

Nursing Mothers: It is not known whether this drug is excreted in human milk; in animal studies brimonidine tartrate was excreted in breast milk. A decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Pediatric Use: In a well-controlled clinical study conducted in pediatric glaucoma patients (ages 2 to 7 years) the most commonly observed adverse events with brimonidine tartrate ophthalmic solution 0.2% dosed three times daily were somnolence (50% - 83% in patients ages 2 to 6 years) and decreased alertness. In pediatric patients 7 years of age or older (>20kg), somnolence appears to occur less frequently (25%). Approximately 16% of patients on brimonidine tartrate ophthalmic solution discontinued from the study due to somnolence.

The safety and effectiveness of Brimonidine tartrate ophthalmic solution have not been studied in pediatric patients below the age of 2 years. Brimonidine tartrate ophthalmic solution is not recommended for use in pediatric patients under the age of 2 years. (Also refer to Adverse Reactions section.)

Geriatric Use: No overall differences in safety or effectiveness have been observed between elderly and other adult patients.

ADVERSE REACTIONS

Adverse events occurring in approximately 10-30% of the subjects, in descending order of incidence, included oral dryness, ocular hyperemia, burning and stinging, headache, blurring, foreign body sensation, fatigue/drowsiness, conjunctival follicles, ocular allergic reactions, and ocular pruritus.

Events occurring in approximately 3-9% of the subjects, in descending order included corneal staining/erosion, photophobia, eyelid erythema, ocular ache/pain, ocular dryness, tearing, upper respiratory symptoms, eyelid edema, conjunctival edema, dizziness, blepharitis, ocular irritation, gastrointestinal symptoms, asthenia, conjunctival blanching, abnormal vision and muscular pain.

The following adverse reactions were reported in less than 3% of the patients: lid crusting, conjunctival hemorrhage, abnormal taste, insomnia, conjunctival discharge, depression, hypertension, anxiety, palpitations/arrhythmias, nasal dryness and syncope.

The following events have been identified during post-marketing use of Brimonidine tartrate ophthalmic solution in clinical practice. Because they are reported voluntarily from a population of unknown size, estimates of frequency cannot be made. The events, which have been chosen for inclusion due to either their seriousness, frequency of reporting, possible causal connection to Brimonidine tartrate ophthalmic solution, or a combination of these factors, include: bradycardia; hypotension; iritis; miosis; skin reactions (including erythema, eyelid pruritus, rash, and vasodilation); and tachycardia. Apnea, bradycardia, hypotension, hypothermia, hypotonia, and somnolence have been reported in infants receiving Brimonidine tartrate ophthalmic solution.

OVERDOSAGE

No information is available on overdosage in humans. Treatment of an oral overdose includes supportive and symptomatic therapy; a patent airway should be maintained.

DOSAGE AND ADMINISTRATION

The recommended dose is one drop of Brimonidine tartrate ophthalmic solution in the affected eye(s) three times daily, approximately 8 hours apart.

Brimonidine tartrate ophthalmic solution may be used concomitantly with other topical ophthalmic drug products to lower intraocular pressure. If more than one topical ophthalmic product is being used, the products should be administered at least 5 minutes apart.

HOW SUPPLIED

Brimonidine tartrate ophthalmic solution 0.2% is supplied sterile in white opaque LDPE plastic bottles and tips with purple high impact polystyrene (HIPS) caps as follows:

5 mL in 10 mL bottle NDC 60758-866-05
10 mL in 10 mL bottle NDC 60758-866-10
15 mL in 15 mL bottle NDC 60758-866-15

NOTE: Store between 15°-25°C (59°-77°F).

Rx only

Revised June 2002

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Irvine, CA 92612, U.S.A.
Printed in U.S.A.
U.S. Pat. 6,194,415; 6,248,741

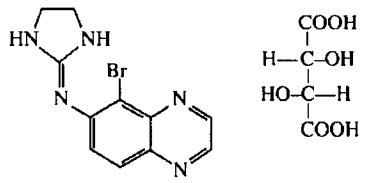
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EXHIBIT F

ALPHAGAN® P
(brimonidine tartrate ophthalmic solution) 0.15%
STERILE

DESCRIPTION

ALPHAGAN® P (brimonidine tartrate ophthalmic solution) 0.15% is a relatively selective alpha-2 adrenergic agonist for ophthalmic use. The chemical name of brimonidine tartrate is 5-bromo-6-(2-imidazolidinylideneamino) quinoxaline L-tartrate. It is an off-white to pale yellow powder. It has a molecular weight of 442.24 as the tartrate salt, and is both soluble in water (1.5 mg/mL) and in the product vehicle (3.0 mg/mL) at pH 7.2. The structural formula is:



Formula: $C_{11}H_{10}BrN_5 \cdot C_4H_6O_6$
CAS Number: 59803-98-4

In solution, **ALPHAGAN® P** (brimonidine tartrate ophthalmic solution) 0.15% has a clear, greenish-yellow color. It has an osmolality of 250-350 mOsmol/kg and a pH of 6.6-7.4.

Each mL of **ALPHAGAN® P** contains:
Active ingredient: brimonidine tartrate 0.15% (1.5 mg/mL)
Preservative: Purite® 0.005% (0.05 mg/mL)
Inactives: boric acid; calcium chloride; magnesium chloride; potassium chloride; purified water; sodium borate; sodium carboxymethylcellulose; sodium chloride; with hydrochloric acid and/or sodium hydroxide to adjust pH.

CLINICAL PHARMACOLOGY

Mechanism of Action: **ALPHAGAN® P** is an alpha adrenergic receptor agonist. It has a peak ocular hypotensive effect occurring at two hours post-dosing. Fluorophotometric studies in animals and humans suggest that brimonidine tartrate has a dual mechanism of action by reducing aqueous humor production and increasing uveoscleral outflow.

Pharmacokinetics: After ocular administration of either a 0.1% or 0.2% solution, plasma concentrations peaked within 0.5 to 2.5 hours and declined with a systemic half-life of approximately 2 hours. In humans, systemic metabolism of brimonidine is extensive. It is metabolized primarily by the liver. Urinary excretion is the major route of elimination of the drug and its metabolites. Approximately 87% of an orally-administered radioactive dose was eliminated within 120 hours, with 74% found in the urine.

Clinical Evaluations: Elevated IOP presents a major risk factor in glaucomatous field loss. The higher the level of IOP, the greater the likelihood of optic nerve damage and visual field loss. Brimonidine tartrate has the action of lowering intraocular pressure with minimal effect on cardiovascular and pulmonary parameters.

Two clinical studies were conducted to evaluate the safety, efficacy, and acceptability of **ALPHAGAN® P** (brimonidine tartrate ophthalmic solution) 0.15% compared with **ALPHAGAN®** administered three-times-daily in patients with open-angle glaucoma or ocular hypertension. Those results indicated that **ALPHAGAN® P** (brimonidine tartrate ophthalmic solution) 0.15% is comparable in IOP lowering effect to **ALPHAGAN®** (brimonidine tartrate ophthalmic solution) 0.2%, and effectively lowers IOP in patients with open-angle glaucoma or ocular hypertension by approximately 2-5 mm Hg.

INDICATIONS AND USAGE

ALPHAGAN® P is indicated for the lowering of intraocular pressure in patients with open-angle glaucoma or ocular hypertension.

CONTRAINDICATIONS

ALPHAGAN® P is contraindicated in patients with hypersensitivity to brimonidine tartrate or any component of this medication. It is also contraindicated in patients receiving monoamine oxidase (MAO) inhibitor therapy.

PRECAUTIONS

General: Although **ALPHAGAN® P** had minimal effect on the blood pressure of patients in clinical studies, caution should be exercised in treating patients with severe cardiovascular disease.

ALPHAGAN® P has not been studied in patients with hepatic or renal impairment; caution should be used in treating such patients.

ALPHAGAN® P should be used with caution in patients with depression, cerebral or coronary insufficiency, Raynaud's phenomenon, orthostatic hypotension, or thromboangiitis obliterans. Patients prescribed IOP-lowering medication should be routinely monitored for IOP.

Information for Patients: As with other drugs in this class, **ALPHAGAN® P** may cause fatigue and/or drowsiness in some patients. Patients who engage in hazardous activities should be cautioned of the potential for a decrease in mental alertness.

Drug Interactions: Although specific drug interaction studies have not been conducted with **ALPHAGAN® P**, the possibility of an additive or potentiating effect with CNS depressants (alcohol, barbiturates, opiates, sedatives, or anesthetics) should be considered. Alpha-agonists, as a class, may reduce pulse and blood pressure. Caution in using concomitant drugs such as beta-blockers (ophthalmic and systemic), anti-hypertensives and/or cardiac glycosides is advised.

Tricyclic antidepressants have been reported to blunt the hypotensive effect of systemic clonidine. It is not known whether the concurrent use of these agents with **ALPHAGAN® P** in humans can lead to resulting interference with the IOP lowering effect. No data on the level of circulating catecholamines after **ALPHAGAN® P** administration are available. Caution, however, is advised in patients taking tricyclic antidepressants which can affect the metabolism and uptake of circulating amines.

Carcinogenesis, Mutagenesis, and Impairment of Fertility: No compound-related carcinogenic effects were observed in either mice or rats following a 21-month and 24-month study, respectively. In these studies, dietary administration of brimonidine tartrate at doses up to 2.5 mg/kg/day in mice and 1.0 mg/kg/day in rats achieved 86 and 55 times, respectively, the plasma drug concentration estimated in humans treated with one drop of **ALPHAGAN® P** into both eyes 3 times per day.

Brimonidine tartrate was not mutagenic or cytogenic in a series of *in vitro* and *in vivo* studies including the Ames test, chromosomal aberration assay in Chinese Hamster Ovary (CHO) cells, a host-mediated assay and cytogenic studies in mice, and dominant lethal assay.

Reproductive studies performed in rats with oral doses of 0.66 mg base/kg revealed no evidence of impaired fertility due to **ALPHAGAN® P**.

Pregnancy: Teratogenic Effects: Pregnancy Category B. Reproductive studies performed in rats with oral doses of 0.66 mg base/kg revealed no evidence of harm to the fetus due to **ALPHAGAN® P**. Dosing at this level produced an exposure that is 189 times higher than the exposure seen in humans following multiple ophthalmic doses.

There are no adequate and well-controlled studies in pregnant women. In animal studies, brimonidine crossed the placenta and entered into the fetal circulation to a limited extent. **ALPHAGAN® P** should be used during pregnancy only if the potential benefit to the mother justifies the potential risk to the fetus.

Nursing Mothers: It is not known whether this drug is excreted in human milk; in animal studies brimonidine tartrate was excreted in breast milk. A decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Pediatric Use: In a well-controlled clinical study conducted in pediatric glaucoma patients (ages 2 to 7 years) the most commonly observed adverse events with brimonidine tartrate ophthalmic solution 0.2% dosed three times daily were somnolence (50% - 83% in patients ages 2 to 6 years) and decreased alertness. In pediatric patients 7 years of age or older (>20kg), somnolence appears to occur less frequently (25%). Approximately 16% of patients on brimonidine tartrate ophthalmic solution discontinued from the study due to somnolence.

The safety and effectiveness of brimonidine tartrate ophthalmic solution have not been studied in pediatric patients below the age of 2 years. Brimonidine tartrate ophthalmic solution is not recommended for use in pediatric patients under the age of 2 years. (Also refer to Adverse Reactions section.)

Geriatric Use: No overall differences in safety or effectiveness have been observed between elderly and other adult patients.

ADVERSE REACTIONS

Adverse events occurring in approximately 10-20% of the subjects included: allergic conjunctivitis, conjunctival hyperemia, and eye pruritus.

Adverse events occurring in approximately 5-9% of the subjects included: burning sensation, conjunctival folliculosis, hypertension, oral dryness, and visual disturbance.

Events occurring in approximately 1-4% of subjects included: allergic reaction, asthenia, blepharitis, bronchitis, conjunctival edema, conjunctival hemorrhage, conjunctivitis, cough, dizziness, dyspepsia, dyspnea, epiphora, eye discharge, eye dryness, eye irritation, eye pain, eyelid edema, eyelid erythema, flu syndrome, follicular conjunctivitis, foreign body sensation, headache, pharyngitis, photophobia, rash, rhinitis, sinus infection, sinusitis, stinging, superficial punctate keratopathy, visual field defect, vitreous floaters, and worsened visual acuity.

The following events were reported in less than 1% of subjects: corneal erosion, insomnia, nasal dryness, somnolence, and taste perversion.

The following events have been identified during post-marketing use of **ALPHAGAN®** in clinical practice. Because they are reported voluntarily from a population of unknown size, estimates of frequency cannot be made. The events, which have been chosen for inclusion due to either their seriousness, frequency of reporting, possible causal connection to **ALPHAGAN®**, or a combination of these factors, include: bradycardia; hypotension; iritis; miosis; skin reactions (including erythema, eyelid pruritus, rash, and vasodilation) and tachycardia. Apnea, bradycardia, hypotension, hypothermia, hypotonia, and somnolence have been reported in infants receiving **ALPHAGAN®**.

OVERDOSAGE

No information is available on overdosage in humans. Treatment of an oral overdose includes supportive and symptomatic therapy; a patent airway should be maintained.

DOSAGE AND ADMINISTRATION

The recommended dose is one drop of **ALPHAGAN® P** in the affected eye(s) three times daily, approximately 8 hours apart.

ALPHAGAN® P may be used concomitantly with other topical ophthalmic drug products to lower intraocular pressure. If more than one topical ophthalmic product is being used, the products should be administered at least 5 minutes apart.

HOW SUPPLIED

ALPHAGAN® P (brimonidine tartrate ophthalmic solution) 0.15% is supplied sterile in opaque teal LDPE plastic bottles and tips with purple high impact polystyrene (HIPS) caps as follows:

5 mL in 10 mL bottle	NDC 0023-9177-05
10 mL in 10 mL bottle	NDC 0023-9177-10
15 mL in 15 mL bottle	NDC 0023-9177-15

NOTE: Store between 15°-25° C (59°-77°F).

Rx Only

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US Patent Nos. 5,424,078; 5,736,165
Revised December 2001
7831X

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(brimonidine tartrate ophthalmic solution) 0.15%