

ADVANCED MEDICAL OPTICS INC

Form 10-K

March 02, 2005

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**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

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**FORM 10-K**

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x **Annual Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**

**For the Fiscal Year Ended December 31, 2004**

or

.. **Transition Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**

Commission File No. 001-31257

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**ADVANCED MEDICAL OPTICS, INC.**

(Exact name of Registrant as Specified in its Charter)

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**Delaware**  
(State of Incorporation)

**33-0986820**  
(I.R.S. Employer Identification No.)

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1700 E. St. Andrew Place,

Santa Ana, California  
(Address of principal executive offices)

92705  
(Zip Code)

Registrant's telephone number: (714) 247-8200

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

<u>Title of each class</u>	<u>Name of each exchange on which each class registered</u>
Common Stock, \$0.01 par value	New York Stock Exchange
Preferred Stock Purchase Rights	

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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 (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  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 voting and non-voting common equity held by non-affiliates is approximately \$1.2 billion based upon the closing price on the New York Stock Exchange as of June 25, 2004.

Common Stock outstanding as of February 28, 2005 37,180,809 shares (including 1,379 shares held in treasury).

**DOCUMENTS INCORPORATED BY REFERENCE**

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Part III incorporates certain information by reference from the registrant's proxy statement for the 2005 annual meeting of stockholders, 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**

AMO was incorporated in Delaware in October 2001 as a subsidiary of Allergan, Inc. (Allergan). Allergan spun-off our company to its stockholders by way of a distribution of all of our shares of common stock on June 29, 2002. As a result of our spin-off from Allergan, we are an independent public company, and Allergan has no continuing stock ownership in us. Unless the context requires otherwise, references to "AMO", the Company, we, us or our refer to Allergan's optical medical device business for the periods prior to June 29, 2002 and to Advanced Medical Optics, Inc. and its subsidiaries for the periods on or after such date.

**Overview**

We are a global leader in the development, manufacture and marketing of medical devices for the eye. We have two major product lines: ophthalmic surgical and eye care. Our ophthalmic surgical product line provides medical devices for use in the cataract and refractive surgery markets. In the cataract surgery market, we focus on the four key products required for cataract surgery – foldable intraocular lenses, or IOLs, implantation systems, phacoemulsification systems and viscoelastics. In the refractive surgery market, in addition to IOLs and viscoelastics, we market microkeratomes for use in the LASIK procedure. Our eye care product line provides a full range of contact lens care products for use with most types of contact lenses. These products include single-bottle, multi-purpose cleaning and disinfecting solutions, hydrogen peroxide-based disinfecting solutions, daily cleaners, enzymatic cleaners and contact lens rewetting drops. In 2004, we began selling contact lenses in Europe, as well. Our products are sold in approximately 60 countries, and we have direct operations in approximately 20 countries.

In June 2004, we completed our acquisition of Pfizer Inc.'s surgical ophthalmic business, which expanded our viscoelastic and IOL product offerings, allowing us to offer a more comprehensive portfolio of products required to perform cataract surgery. We acquired the *Healon* family of viscoelastic products and the *Tecnis* and *CeeOn* IOL brands. The addition of the *Healon* family, one of the leading viscoelastic brands, significantly expanded our viscoelastic product line. The *Tecnis* and *CeeOn* IOL brands further strengthened our position in the ophthalmic surgery market with the *Tecnis* multifocal IOL brand expanding our product offerings into the refractive correction market. We also acquired the *Baerveldt* glaucoma shunt, or drainage device, which provided an entry for us into the glaucoma market.

In November 2004, we entered into an agreement with VISX, Incorporated, the global leader in laser vision correction, to acquire the company for a combination of cash and stock with an estimated value of approximately \$1.3 billion on the announcement date. VISX manufactures excimer laser systems, associated diagnostic devices, and treatment cards. Under the terms of the definitive merger agreement, VISX stockholders are expected to receive 0.552 shares of Company common stock and \$3.50 in cash for every share of VISX common stock they own. We expect to complete the acquisition during the second quarter of 2005. For a description of the risks related to this transaction, see "Risks Relating to the Merger with VISX, Incorporated" beginning on page 22.

**Industry**

***Vision and Vision Impairment.***

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*How Vision Works.* Vision is generated by the cornea and the lens, which work together to focus light, and the iris, which regulates the amount of light that passes through the cornea onto the retina. The retina contains light-sensitive receptors that transmit the image through the optic nerve to the brain.

*Cataracts.* Cataracts are an irreversible progressive ophthalmic condition in which the eye's natural lens loses its usual transparency and becomes clouded and opaque. This clouding obstructs the passage of light to the retina and can eventually lead to blindness.

*Refractive Disorders.* Refractive disorders, such as myopia, hyperopia, astigmatism and presbyopia, occur when the lens system is unable to properly focus images on the retina. For example, with myopia (nearsightedness), light rays focus in front of the retina because the curvature of the cornea is too steep. With hyperopia (farsightedness), light rays focus behind the retina because the curvature of the cornea is too flat. Astigmatism makes it difficult for a person to focus on any object because the otherwise uniform curvature of the cornea is somehow disrupted or

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becomes uneven. Presbyopia is the progressive loss of flexibility of the lens and its ability to change shape to focus on near or far objects, and is presumably caused by aging of the eye's lens and the muscles that control the shape of the lens. In the United States, approximately 166 million people suffer from some type of refractive disorder.

*Ophthalmic Surgical Products Market.* Ophthalmic surgical products generally are designed to correct impaired vision through minimally invasive surgical procedures. As the eye ages, the prevalence of cataracts and refractive disorders generally increases. We believe that an aging population, introduction of new technologies and increasing market acceptance present opportunities for growth in the ophthalmic surgical market.

*Cataract Treatment.* The largest segment of the ophthalmic surgical products market is the treatment of cataracts. Cataract extraction followed by IOL implantation is one of the most common surgical procedures performed in the United States and most other developed nations. As estimated by MarketScope, approximately 2.7 million cataract procedures were performed in the United States and over 14.3 million cataract procedures were performed worldwide in 2004. MarketScope estimates that the global cataract surgery market, which includes sales of IOLs, phacoemulsification equipment, viscoelastics and other related products, was approximately \$2.6 billion in 2004 and is projected to grow at a compound annual growth rate of approximately 6% from 2004 to 2009. The data in this report attributed to MarketScope is used with the permission of MarketScope.

During cataract surgery, patients are often treated using phacoemulsification, a process that uses ultrasound waves to break the natural lens into tiny fragments that can be removed from the eye. Viscoelastics are used during cataract surgery to protect the inner layer of the cornea, provide lubrication and maintain space in the capsular bag (which houses the lens), allowing the eye to maintain its shape.

The following table sets forth the estimated revenues for each component of the global cataract surgery market in its various components for the year 2004 according to MarketScope (in millions):

IOLs	\$ 1,066
Viscoelastics	479
Phacoemulsification machines and accessories	260
Other	800
<b>Total</b>	<b>\$ 2,605</b>

*Refractive Vision Correction.* Another segment of the ophthalmic surgical market is the surgical treatment of refractive disorders.

*LASIK.* The most common surgical technique for treating refractive disorders is laser assisted in-situ keratomileusis, or LASIK. LASIK involves the use of an automated cutting device to cut a thin corneal flap, which is then pulled back to expose the underlying tissue, which is treated using an excimer laser to achieve vision correction. The most common cutting device is called a microkeratome.

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*IOLs.* Surgical implantation of IOLs may be used to treat those patients with refractive disorders that cannot be treated with LASIK. For example, a patient with a thin cornea may not be recommended for LASIK treatment, but could be eligible for a phakic IOL. Phakic IOLs can be implanted in front or in back of the iris and work in conjunction with the patient's natural lens to treat refractive disorders. Other procedures, such as replacing the patient's natural lens with an accommodating IOL for refractive vision correction, are also being developed.

*Eye Care Market.* As the use of contact lenses has become increasingly popular, the demand for disinfecting solutions, daily cleaners, enzymatic cleaners and contact lens rewetting drops has increased. We believe that the contact lens care industry is growing as a result of broader acceptance among younger wearers and continued improvement in contact lens and contact lens care technologies. In addition, in response to increasing popularity of more frequently replaceable lenses and consumer interest in more convenient lens care regimens, we believe the contact lens care market continues to evolve towards greater use of single-bottle, multi-purpose solutions.



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### Our Products

#### *Ophthalmic Surgical Product Line*

Our ophthalmic surgical products business develops, manufactures and markets medical devices for the cataract and refractive surgery markets, with a focus on technologically advanced products.

#### *Cataract Surgery*

We focus on the four key devices for the cataract surgery market:

*Foldable IOLs* Foldable IOLs are artificial lenses used to replace the human lens.

*Implantation systems* Implantation systems are designed and used specifically to implant IOLs during cataract surgery.

*Phacoemulsification systems* Phacoemulsification systems use ultrasound during small incision cataract surgery to break apart and remove the cloudy human lens prior to its replacement with an IOL.

*Viscoelastics* Viscoelastics provide a barrier of protection for the cornea during phacoemulsification and maintain the shape of the eye during IOL insertion.

*Intraocular Lenses.* As a leading provider of IOLs, we offer surgeons a choice of high quality, innovative foldable IOLs in both acrylic and silicone, together with our proprietary implantation systems, for use in minimally invasive cataract surgical procedures. We are the only company that offers a selection of IOLs in both silicone and acrylic materials in the United States, and we offer both monofocal and multifocal designs. Sales of our IOLs represented approximately 32%, 34% and 34% of our net sales in 2004, 2003 and 2002, respectively. Our IOLs include:

*Tecnis* the only foldable IOL with an aspheric surface and the only IOL to receive FDA approval for claims of improved functional vision, which results in quicker recognition of objects in lower-light conditions. *Tecnis* Multifocal is approved in Europe for treatment of presbyopia. We acquired this product from Pfizer in June 2004.

*Sensar* an acrylic monofocal IOL, with the patented *OptiEdge* design, intended to reduce post-surgical posterior capsular opacification, in order to lessen the need for subsequent corrective laser procedures, and to reduce the potential for unwanted glare and reflections following implantation.

*ClariFlex* a silicone monofocal IOL, also with the *OptiEdge* design.

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*PhacoFlex II* a line of silicone monofocal IOLs.

*Array, Array II and ReZoom* a silicone or acrylic multifocal IOL with optical zones that provide near, intermediate and distance vision, reducing that patient's dependence on eyeglasses. The *Array* and *ReZoom* IOLs are also approved in Europe for the treatment of presbyopia.

*CeeOn* a brand of IOL that is available in both a foldable and PMMA, or non-foldable, version. We also acquired this product from Pfizer.

*Implantation Systems.* As a companion to our foldable IOLs, we market insertion systems for each of our foldable IOL models. The *Unfolder*, our proprietary series of implantation systems, which includes the *Emerald*, *SilverT* and *Silver* implantation systems, is used for insertion of our foldable IOLs. These systems assist the surgeon in achieving controlled release of the intraocular lens into the capsular bag through a small incision in the eye.

*Phacoemulsification Systems.* We are a leading provider of phacoemulsification systems, and have a range of systems to meet market needs. Phacoemulsification systems use disposable or reusable packs that are necessary to operate the equipment. The majority of our phacoemulsification product sales are from sales of these packs and related accessories. Sales of our phacoemulsification products represented approximately 10%, 11% and 11% of our net sales in 2004, 2003 and 2002, respectively.

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We currently market the following phacoemulsification systems:

*Sovereign* our premier phacoemulsification system is designed to reduce procedure times and provide the surgeon with increased control. The *Sovereign* system is available with our proprietary Occlusion Mode and *WhiteStar* technology, which creates less heat and turbulence in the ocular environment, giving rise to the term "cold phaco" and enabling better patient outcomes. Our *WhiteStar* technology also permits the system to offer bimanual, micro-incision phaco, a procedure which gives surgeons more operating flexibility over traditional techniques.

*Sovereign Compact* is a mid-sized phacoemulsification system designed to meet surgeons' needs for an advanced phacoemulsification system, with the same functionality of the *Sovereign* system, in a smaller, more portable size. The *Sovereign Compact* system is also available with Occlusion Mode and *WhiteStar* technology.

*The Diplomax* and *Prestige* our more affordable phacoemulsification systems that are currently positioned primarily for markets outside the United States. These systems provide more basic options as compared to the *Sovereign* and *Sovereign Compact* systems while providing the necessary control during the procedure.

*Viscoelastics.* We acquired from Pfizer in June 2004 the *Healon* family of viscoelastics, and as a result are a leading provider of viscoelastic products. The *Healon* family is one of the leading brands of viscoelastics and has significantly expanded the scale of our existing viscoelastic offering, which includes our *Vitrax* and *Vitrax II* brands of viscoelastic. The different characteristics associated with each *Healon* product, *Healon*, *Healon GV* and *Healon5*, provide surgeons with a range of viscoelastic choices that combine the familiarity of the *Healon* line with advanced technologies to satisfy different surgical needs. *Healon* was the first viscoelastic introduced into the ophthalmic surgical product market and is known for its purity and ease of use. *Healon GV* is of a greater viscosity than the original *Healon* solution, which is designed for certain ophthalmic surgical procedures. *Healon5* is the first and only viscoadaptive agent to exhibit properties of both cohesive and dispersive viscoelastics. *Healon5* has the highest viscosity of any viscoelastic currently available and is designed to create and maintain a deep anterior chamber during surgery, which facilitates manipulation inside the eye. Our *Vitrax* product complements the *Healon* family to meet a full range of needs during surgery. *Vitrax* is a low molecular weight dispersive viscoelastic used during the phacoemulsification process to protect the cornea. Sales of our viscoelastic products represented approximately 10%, 3% and 2% of our net sales in 2004, 2003 and 2002, respectively.

*Other Cataract Surgical Related Products.* In addition to our IOLs, phacoemulsification equipment and viscoelastics, we also provide several ancillary products related to the cataract surgery market, including:

*Irrigating Solutions.* We offer irrigating solutions for use in cataract surgery to help maintain space in the eye and to aid in removing residual tissue during phacoemulsification. Irrigating solutions are balanced saline solutions that are compatible with the natural fluid of the anterior segment of the eye.

*Custom Eye Trays.* We work with partners in our local markets to offer custom eye trays to our customers. These custom eye trays typically consist of all of the ancillary items that a surgeon needs to use in a single cataract surgery, such as surgical knives, drapes, gloves and gowns. Our partners typically handle assembly, distribution and billing for the product and in most cases we receive a fee per tray from our partners.

*Capsular Tension Rings.* In the United States, we sell the *StabilEyes* capsular tension ring, which is inserted into the capsular bag during cataract surgery and functions to stabilize the capsular bag during placement of an IOL. We also market and distribute the *Inject-o-Ring* capsular tension ring in Europe. We distribute these products under arrangements with Ophtec B.V. in the United States and Corneal in Europe, respectively.

*Refractive Surgery*

The most common refractive surgery procedure is laser surgery.

In the refractive surgery market, we are a worldwide distributor of the *Amadeus* and *Amadeus II* microkeratome system and *SurePass* microkeratome blades, which have the most predictable outcomes in our industry. Surgeons use microkeratomes in LASIK procedures to cut a flap of corneal tissue before treatment with an excimer laser. We also have an exclusive co-marketing agreement in the United States with VISX, Incorporated, which sells excimer laser systems.

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In Europe, we market our *Verisyse*, *ReZoom*, *Array* and *Tecnis* multifocal IOLs for refractive procedures. The *Verisyse* IOL is an implant that works in combination with the natural lens for the correction of refractive errors, such as nearsightedness. We also have recent FDA approval for the *Verisyse* phakic IOL in the United States.

### *Other Surgical Products*

*Glaucoma Implant.* The *Baerveldt* glaucoma implant is indicated for use in patients with medically uncontrollable glaucoma and a poor surgical prognosis due to severe preexisting conditions. This can include: neovascular glaucoma, aphakic/pseudophakic glaucoma, failed conventional surgery, congenital glaucoma, and secondary glaucoma due to uveitis or epithelial down growth. *Baerveldt* glaucoma implants are available in three models, all of which feature a larger surface area plate than competing single-quadrant devices.

### *Eye Care Product Line*

In the eye care market, we focus on creating products that make contact lenses more comfortable and simplify contact lens care and promote ocular health. Our eye care business develops, manufactures and markets a full range of contact lens care products for use with most types of contact lenses. Our comprehensive product offering includes single-bottle, multi-purpose cleaning and disinfecting solutions and hydrogen peroxide-based disinfecting solutions to destroy harmful microorganisms in and on the surface of contact lenses; daily cleaners to remove undesirable film and deposits from contact lenses; enzymatic cleaners to remove protein deposits from contact lenses; and lens rewetting drops to provide added wearing comfort.

*Multi-Purpose Solutions.* We market our *Complete* brand single-bottle multi-purpose solutions, a convenient, one bottle chemical disinfecting system for soft contact lenses, on a worldwide basis. *Complete MoisturePLUS* is the first single-bottle, multi-purpose solution with dual demulcents to help prevent contact lens dryness and discomfort and promote ocular health. Sales of our multi-purpose solutions represented approximately 21%, 23% and 22% of our net sales in 2004, 2003 and 2002, respectively. We also offer *Complete Blink-N-Clean*, a unique in-the-eye lens cleaning solution.

*Hydrogen Peroxide-Based Solutions.* We offer products that use hydrogen peroxide-based disinfection systems. Our leading hydrogen peroxide brands are the *Oxysept 1 Step*, *Ultracare*, *Consept 1 Step* and *Consept F* solutions. Sales of our hydrogen peroxide-based solutions represented approximately 14%, 16% and 18% of our net sales in 2004, 2003 and 2002, respectively.

*Lens Rewetting Solutions.* We believe that dryness and discomfort are the reasons most often cited for discontinuing contact lens wear. We have introduced contact lens rewetting drops designed to provide prolonged lubrication and improved protection against dryness. Our products in this category include *Complete* and *blink* rewetting solutions.

*Contact Lenses.* In 2004, we entered the contact lens business outside of the United States with the introduction of the *AquaVision* monthly disposable contact lens.

## Research and Development

Our long-term success is dependent on the introduction of new and innovative products in both the ophthalmic surgical and eye care businesses. Our research and development strategy is to develop proprietary products for vision correction that are safe and effective and address unmet needs. As we implement this strategy, we will seek to develop new products with measurable benefits such as increased practitioner productivity, better patient outcomes and reduced costs to health care payors and providers.

Research and development activities for our ophthalmic surgical business are focused on expanding our product portfolio for both cataract and refractive surgery. Within cataract surgery, we have focused on six areas of opportunity to provide superior outcomes:

*Small incision surgery* work with a variety of advanced lens materials to enable small incision surgery which results in less induced astigmatism, rapid stabilization of the wound and faster visual rehabilitation.

*Advances in phacoemulsification* technology providing surgeons with high levels of cutting efficiency but with less heat and turbulence directed into the ocular environment enabling potential for more effective and safer cataract extraction procedures.

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*Restoring accommodation following cataract surgery* following cataract surgery, the eye may lose its ability to accommodate, or shift its field of focus.

*Improving quality of vision* advancements in optics and optical surface designs.

*Reducing posterior capsular opacification, or PCO, following cataract surgery* PCO is a clouding of the posterior portion of the intraocular lens that occurs in some patients following cataract surgery. Currently, treatment of moderate to severe PCO typically requires a laser procedure.

*Greater ease of use for practitioners* development of advanced insertion devices which allow for easier handling in the operating room and greater surgeon control.

Current projects include expansion of our portfolio of IOLs with the launch of a new multifocal IOL, *ReZoom*, an acrylic version of the *Tecnis* IOL, and a next generation *Sensar* IOL. Other projects include developing easier to use insertion systems for our foldable IOLs that provide for faster and safer procedures, and advances to our high end phacoemulsification system including our proprietary *WhiteStar* software technology.

In addition to cataract surgery products, we are leveraging our expertise in IOL implant technology to the areas of the surgical correction of refractive errors such as the *Verisyse* phakic IOL. These areas represent large unmet needs that are not addressed by current surgical procedures. Products that are currently under development include refractive implants for correction of moderate to high myopia and presbyopia.

Our research and development efforts in the eye care business are aimed at developing proprietary systems that are effective and more convenient for customers to use, which we believe will result in longer, more comfortable lens wear and a higher rate of compliance with recommended lens care procedures. Our efforts include seeking formulations that provide prolonged lubrication, improved protection against dryness and enhanced cleaning without irritation and ocular health. Our research and development efforts have resulted in the continued development of our flagship *Complete* brand multi-purpose solution and *blink* rewetter solutions, with further advancements currently in development.

We plan to supplement our research and development activities with a commitment to identifying and obtaining new technologies through in-licensing, technological collaborations and joint ventures, including the establishment of research relationships with academic institutions and individual researchers.

We spent approximately \$45.6 million in 2004, \$37.4 million in 2003, and \$29.9 million in 2002 on research and development. Total research and development expense in 2004 was \$73.7 million, including a non-cash in-process research and development charge of \$28.1 million. Research and development spending represented 6.1%, 6.2%, and 5.6% of total net sales in 2004, 2003, and 2002, respectively. We believe that the continuing introduction of new products supplied by our research and development efforts and in-licensing opportunities are critical to our success. There are, however, inherent uncertainties associated with the research and development efforts and the regulatory process and we cannot assure you that any of our research projects will result in new products that we can commercialize.

## **Customers, Sales and Marketing**

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*Customers.* Our primary customers for our ophthalmic surgical products include surgeons who perform cataract surgeries, hospitals and ambulatory surgical centers. The primary customers for our eye care products include optometrists, opticians, ophthalmologists, retailers and clinics that sell directly to consumers. These retailers include mass merchandisers such as Wal-Mart, drug store chains such as Walgreen, hospitals, commercial optical chains and food stores. During 2004, no customer accounted for over 10% of our net sales.

*Sales and Marketing.* Our sales efforts and promotional activities with respect to our ophthalmic surgical products are primarily aimed at eye care professionals such as ophthalmologists who use our products. Similarly, our sales and promotional efforts in contact lens care are primarily directed towards optometrists, opticians and ophthalmologists. We often provide samples of our eye care products to practitioners to distribute to their patients to encourage trial use of our solutions. In addition, we advertise in professional journals and have a direct mail program of descriptive product literature and scientific information that we provide to specialists in the eye care field. We have also developed training modules and seminars to update physicians regarding evolving technology. A number of our marketing programs include peer-to-peer marketing with practitioners educating other practitioners about the benefits of our products.



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Recognizing the importance of our sales force's expertise, we invest significant time and expense to provide training in such areas as product features and benefits. Training for our ophthalmic surgical products sales force focuses on providing sales personnel with technical knowledge regarding the scope and characteristics of the products they are selling and developing skills in presenting and demonstrating those products. In addition to providing product knowledge for communication to eye care practitioners, our eye care products sales force focuses on developing the necessary skills to sell to buyers for mass merchandisers and large drug store chains. This sales force also seeks to develop relationships with eye care professionals who may purchase our products and recommend them to their patients.

Each of our products is marketed under its brand name and our corporate name. We have a worldwide marketing organization which helps us to set overall marketing direction, promote consistent global brand positioning and allocate marketing resources to products and regions offering the greatest return. In order to remain sensitive to cultural differences and varying health care systems throughout the world, tactical execution of marketing programs and all sales activities are carried out at the regional level.

We also use third-party distributors for the distribution of our products in smaller geographic markets. No individual agent or distributor accounted for more than 10% of our net sales for the year ended December 31, 2004.

Traditionally, we have realized a seasonal trend in our sales, with the smallest portion of our ophthalmic surgical business sales being realized in the first quarter and with sales gradually increasing from the second to fourth quarter. This has been driven predominantly by seasonality in the sales of capital equipment when customers increase spending as they reach their year end and are able to spend the remainder of their annual budgeted amounts. We expect to realize less seasonality in future periods as we seek to diversify our sales geographically and with more products that are less seasonal.

## **Manufacturing, Operations and Facilities**

We manufacture eye care products at our facilities in Hangzhou, China, and Madrid, Spain, and we manufacture surgical products at our facilities in Añasco, Puerto Rico, Groningen, Netherlands, Uppsala, Sweden, and Bangalore, India. As part of our separation from Allergan, we entered into an agreement with Allergan under which Allergan manufactures eye care products for us at their facilities in Waco, Texas, Westport, Ireland, and Guarulhos, Brazil. Under this agreement, Allergan also manufactures our ophthalmic surgical product, *Vitrx*, at its Westport, Ireland facility. The manufacturing agreement will terminate on June 29, 2005. As a result, we are transitioning products manufactured by Allergan to our Spain and China plants and to other third-party suppliers. However, while we are confident in our ability to complete the transition, certain events or regulatory issues in validation and scale-up may delay the transition. If we are unable to transition production from Allergan in a timely manner, our business may be negatively impacted in a material way. As part of the transition from Allergan, in November 2003, we entered into an agreement with Nicholas Piramal India Limited for the supply of neutralizing tablets primarily used with our hydrogen-peroxide lens care products and unit dose solutions. Nicholas Piramal will be a sole-source supplier of these products. If supply of these products were interrupted, we cannot assure you that we would be able to obtain replacement products, and our eye care product sales may be negatively impacted in a material manner.

We have historically outsourced the manufacture of our phacoemulsification equipment to third parties: Our *Sovereign* system is manufactured by Carl Zeiss Ophthalmic Systems under a manufacturing and supply agreement. The agreement terminates in May 2005, but we expect to extend the supply relationship. Our *Sovereign Compact* system is manufactured by Sanmina-SCI under a manufacturing and supply agreement, which terminates in December 2007. If Carl Zeiss Ophthalmic Systems or Sanmina-SCI were to cease manufacturing any of these systems for any reason, we cannot assure you that we would be able to replace them on terms favorable to us, or at all.

**Governmental Regulation**

*United States.* Our products and operations are subject to extensive and rigorous regulation by the FDA. The FDA regulates the research, testing, manufacturing, safety, labeling, storage, recordkeeping, promotion, distribution and production of medical devices in the United States to provide reasonable assurance that medical products distributed domestically are safe and effective for their intended uses. The Federal Trade Commission also regulates the advertising of our products.

Under the Federal Food, Drug, and Cosmetic Act, medical devices are classified into one of three classes – Class I, Class II or Class III depending on the degree of risk associated with each medical device and the extent of control needed to provide reasonable assurances with respect to safety and effectiveness. Our current products are Class I, II and III medical devices, with most being classified as Class II devices and our IOLs being classified as Class III devices in the United States, subject to certain exceptions.

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Class I devices are those for which safety and effectiveness can be reasonably assured by adherence to a set of guidelines, which include compliance with the applicable portions of the FDA's Quality System Regulation, facility registration and product listing, reporting of adverse medical events, and appropriate, truthful and non-misleading labeling, advertising, and promotional materials, referred to as the general controls. Some Class I, also called Class I reserved, devices also require premarket clearance by the FDA through the 510(k) premarket notification process described below. Many Class I products are exempt from the premarket notification requirements.

Class II devices are those which are subject to the general controls and may require adherence to certain performance standards or other special controls (as specified by the FDA) and clearance by the FDA: Premarket review and clearance by the FDA for these devices is accomplished through the 510(k) premarket notification procedure. For most Class II devices, the manufacturer must submit to the FDA a premarket notification, demonstrating that the device is substantially equivalent to a legally marketed device.

If the FDA agrees that the device is substantially equivalent, it will grant clearance to commercially market the device. By regulation, the FDA is required to complete its review of a 510(k) within 90 days of submission of the notification. As a practical matter, clearance often takes longer. The FDA may require further information, including clinical data, to make a determination regarding substantial equivalence. If the FDA determines that the device, or its intended use, is not substantially equivalent, the FDA will place the device, or the particular use of the device, into Class III, and the device sponsor must then fulfill much more rigorous premarketing requirements, known as premarket approval.

A Class III product is a product which has a new intended use or uses advanced technology that is not substantially equivalent to a use or technology with respect to a legally marketed device, or for which there is not sufficient information to establish performance standards or special controls to provide reasonable assurance of the device's safety and effectiveness and the product is represented to be for use in supporting or sustaining human life or for a use that is of substantial importance in preventing impairment of human health or presents a potential unreasonable risk of illness or injury. The safety and effectiveness of Class III devices cannot be reasonably assured solely by the general controls and the other requirements described above. Therefore, these devices almost always require formal clinical studies to demonstrate safety and effectiveness.

FDA approval of a premarket approval application is required before marketing a Class III product. The premarket approval application process is much more demanding than the 510(k) premarket notification process. A premarket approval application, which is intended to provide reasonable assurance that the device is safe and effective, must be supported by extensive data, including data from preclinical studies and human clinical trials and existing research material, and must contain a full description of the device and its components, a full description of the methods, facilities and controls used for manufacturing, and proposed labeling. Following receipt of a premarket approval application, once the FDA determines that the application is sufficiently complete to permit a substantive review, the FDA will accept the application for review. The FDA, by statute and by regulation, has 180 days to review a filed premarket approval application, although the review of an application more often occurs over a significantly longer period of time, up to several years.

In approving a premarket approval application or clearing a 510(k) notification, the FDA may also require some form of postmarket surveillance, whereby the manufacturer follows certain patient groups for a number of years and makes periodic reports to the FDA on the clinical status of those patients when necessary to protect the public health or to provide additional safety and effectiveness data for the device.

When FDA approval of a device requires human clinical trials, and if the clinical trial presents a significant risk (as defined by the FDA) to human health, the device sponsor is required to file an investigational device exemption, or IDE, application with the FDA and obtain investigational device exemption approval prior to commencing the human clinical trial. If the clinical trial is considered a nonsignificant risk, investigational device exemption submission to the FDA is not required. Instead, only approval from the Institutional Review Board overseeing the clinical trial is required, although the study is still subject to FDA oversight under other provisions of the IDE regulation. Human clinical studies are generally required in connection with approval of Class III devices and to a much lesser extent for Class I and II devices. Clinical

trials conducted abroad must also comply with local regulations.

*Continuing Food and Drug Administration Regulation.* After the FDA permits a device to enter commercial distribution, numerous regulatory requirements apply. These include:

the registration and listing regulation, which requires manufacturers to register all manufacturing facilities and list all medical devices placed into commercial distribution;

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the Quality System Regulation, which requires manufacturers to follow elaborate design, testing, control, documentation and other quality assurance procedures during the manufacturing process;

labeling regulations;

the FDA's general prohibition against promoting products for unapproved or off-label uses; and the Medical Device Reporting regulation, which requires that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to reoccur;

Medical Device Reporting and recall requirements;

Device tracking requirements; and

Post Market surveillance requirements.

Failure to comply with the applicable U.S. medical device regulatory requirements could result in, among other things, warning letters, fines, injunctions, civil penalties, repairs, replacements, refunds, recalls or seizures of products, total or partial suspension of production, the FDA's refusal to grant future premarket clearances or approvals, withdrawals or suspensions of current product applications, and criminal prosecution.

*Governmental Reimbursement.* In the United States, a significant percentage of the patients who receive our IOLs are covered by the federal Medicare program. When a cataract extraction with IOL implantation is performed in an ambulatory surgical center, Medicare provides the ambulatory surgical center with a fixed facility fee that includes a recommended \$150 allowance to cover the cost of the IOL. After the Centers for Medicare and Medicaid Services (CMS) (formerly the Health Care Financing Administration), awarded new technology intraocular lens status to our *Array* multifocal IOL in 2000, the reimbursement rate for our *Array* multifocal IOLs implanted in ambulatory surgical centers increased to \$200 until May 2005. When the procedure is performed in a hospital outpatient department, the hospital's reimbursement is determined based on the cost of the hospital resources used blended with the cost of the IOLs.

At the end of 2003, Congress enacted the Medicare Prescription Drug Improvement and Modernization Act of 2003. Among other things, this legislation requires CMS to establish a new Medicare payment system for services performed in ambulatory surgical centers. This payment system is to be effective no sooner than January 1, 2006, and no later than January 1, 2008. At this time, it is not possible to determine how this new payment system could affect our revenues or financial condition.

In addition, if implemented, price controls or other cost-containment measures could materially and adversely affect our revenues and financial condition.

We cannot predict the likelihood or pace of any other significant legislative or regulatory 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. In general, however, we believe that legislative and regulatory initiatives will likely continue, and the adoption of new payment or coverage policies can have some impact on our business.

*International Regulation.* Internationally, the regulation of medical devices is also complex. In Europe, our products are subject to extensive regulatory requirements. The regulatory regime in the European Union for medical devices became mandatory in June 1998. It requires that medical devices may only be placed on the market if they do not compromise safety and health when properly installed, maintained and used in accordance with their intended purpose. National laws conforming to the European Union's legislation regulate our IOLs and eye care products under the medical devices regulatory system, rather than the more variable national requirements under which they were formerly regulated. The European Union medical device laws require manufacturers to declare that their products conform to the essential regulatory requirements after which the products may be placed on the market bearing the CE marking. The manufacturers' quality systems for

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products in all but the lowest risk classification are also subject to certification and audit by an independent notified body. In Europe, particular emphasis is being placed on more sophisticated and faster procedures for the reporting of adverse events to the competent authorities.

In Japan, premarketing approval and clinical studies are required, as is governmental pricing approval for medical devices. Clinical studies are subject to a stringent Good Clinical Practices standard. Approval time frames from the Japanese Ministry, Health, Labor and Welfare (MHLW) vary from simple notifications to review periods of one or more years, depending on the complexity and risk level of the device. In addition, importation into Japan of medical devices is subject to Good Import Practices regulations. As with any highly regulated market, significant changes in the regulatory environment could adversely affect future sales.

In many of the other foreign countries in which we market our products, we may be subject to regulations affecting, among other things:

product standards;

packaging requirements;

labeling requirements;

quality system requirements;

import restrictions;

tariff regulations;

duties; and

tax requirements.

Many of the regulations applicable to our devices and products in these countries are similar to those of the FDA. In many countries, the national health or social security organizations require our products to be qualified before they can be marketed with the benefit of reimbursement eligibility.

*Fraud and Abuse.* We are subject to various federal and state laws pertaining to health care fraud and abuse, including anti-kickback laws, physician self-referral laws, and false claims laws. Violations of these laws are punishable by criminal and/or civil sanctions, including, in some instances, imprisonment and exclusion from participation in federal and state health care programs, including Medicare, Medicaid, Veterans Administration (VA) health programs and TRICARE. Although we believe that our operations are in material compliance with such laws, we can give no assurances as these laws are far-reaching and their interpretation changes. In addition, we could be required to alter one or more of our practices to be in compliance with these laws. The occurrence of one or more violations of these laws could result in a material adverse effect on our financial condition and results of operations.

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*Anti-Kickback Laws.* Our operations are subject to federal and state anti-kickback laws. Provisions of the Social Security Act, commonly known as the Anti-Kickback Law, prohibit entities, such as our company, from knowingly and willfully offering, paying, soliciting or receiving any form of remuneration in return for, or to induce:

the referral of persons eligible for benefits under a federal health care program, including Medicare, Medicaid, the VA health programs and TRICARE, or a state health program; or

the recommendation, purchase, lease or order of items or services that are covered, in whole or in part, by a federal health care program or state health programs.

The Anti-Kickback Law may be violated when even one purpose, as opposed to a primary or sole purpose, of a payment is to induce referrals or other business. Federal regulations create a small number of safe harbors. Practices which meet all the criteria of an applicable safe harbor will not be deemed to violate the statute; practices that do not satisfy all elements of a safe harbor do not necessarily violate the statute, although such practices may be subject to scrutiny by enforcement agencies.



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Violation of the Anti-Kickback Law is a felony, punishable by substantial fines and (for individuals) imprisonment. In addition, the Department of Health and Human Services may impose civil penalties and exclude violators from participation in federal or state health care programs (including Medicare, Medicaid, VA health programs, and TRICARE); if a manufacturer is excluded, its products are not eligible for reimbursement by these programs. Many states have adopted similar anti-kickback laws, which vary in scope and may extend to payments intended to induce the recommendation, purchase, or order of products reimbursed by private payors as well as federal or state health care programs.

## **Employee Relations**

At December 31, 2004, we employed approximately 2,865 persons throughout the world, including approximately 565 in the United States. None of our U.S.-based employees are represented by unions. We consider our relations with our employees to be, in general, very good.

## **Global Sales**

Net sales in the United States were approximately \$186.9 million, \$153.5 million, and \$151.3 million for the years ended December 31, 2004, 2003 and 2002, respectively. Our international sales represented approximately \$555.2 million, \$448.0 million, and \$386.8 million for the years ended December 31, 2004, 2003 and 2002, respectively, or 75%, 74%, and 72% of total sales, respectively. Sales in Japan were approximately \$191.5 million, \$164.1 million, and \$145.1 million for the years ended December 31, 2004, 2003 and 2002, respectively. Our products are sold in over 60 countries. Sales are attributed to the country where the customer resides. Marketing activities are coordinated on a worldwide basis, and resident management teams provide leadership and infrastructure for introduction of new products in the local markets. For additional information relating to our geographic operating segments, see Note 13 of Notes to Consolidated Financial Statements.

## **Raw Materials**

We use a diverse and broad range of raw materials in the design, development and manufacture of our products. While we do fabricate or formulate some of our materials at our manufacturing facilities, we purchase most of the materials and components used in manufacturing our products from external suppliers. In addition, we purchase some supplies from single sources for reasons of quality assurance, sole source availability, cost effectiveness or constraints resulting from regulatory requirements. Five of our materials are sole sourced, including the source of hyaluronic acid used in manufacturing our *Healon* family of products. However, we work closely with our suppliers to assure continuity of supply while maintaining high quality and reliability. Where we buy a material from one source and other sources are available, alternative supplier options are generally considered and identified, although we do not typically pursue regulatory qualification of alternative sources due to the strength of our existing supplier relationships and the time and expense associated with the regulatory process. A change in suppliers could require significant effort or investment by us in circumstances where the items supplied are integral to the performance of our products or incorporate unique technology.

## **Environmental Matters**

Our facilities and operations are subject to federal, state and local environmental and occupational health and safety requirements of the United States and foreign countries, including those relating to discharges of substances to the air, water and land, the handling, storage and disposal of wastes and the cleanup of properties affected by pollutants. We believe we are currently in material compliance with such requirements and do

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not currently anticipate any material adverse effect on our business or financial condition as a result of our efforts to comply with such requirements.

In the future, federal, state or local governments in the United States or foreign countries could enact new or more stringent laws or issue new or more stringent regulations concerning environmental and worker health and safety matters that could affect our operations. Also, in the future, contamination may be found to exist at our current or former facilities or off-site locations where we have sent wastes. We could be held liable for such newly-discovered contamination which could have a material adverse effect on our business or financial condition. In addition, changes in environmental and worker health and safety requirements could have a material effect on our business or financial condition.

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### **Competition**

The markets for our ophthalmic surgical device and eye care products are intensely competitive and are subject to significant technological change. Companies within the ophthalmic surgical device market compete on technological leadership and innovation, quality and efficacy of products, relationships with eye care professionals and health care providers, breadth and depth of product offering and pricing. We believe we have the second largest ophthalmic surgical device business on a global basis behind Alcon, Inc., a subsidiary of Nestle S.A. Other competitors in the ophthalmic surgical device business include Bausch & Lomb, Staar Surgical, Moria, IntraLase and Eyeonics. We believe our competitive position is enhanced by our global distribution network, our focus on technology and customer relationships and product quality. Our ability to compete against larger companies may be impeded by having fewer resources to devote to research and development, sales and marketing.

Companies within the eye care market compete primarily on recommendations from eye care professionals, customer brand loyalty, product quality and pricing. We believe we have the second largest contact lens care business on a global basis behind Alcon. Other competitors include Bausch & Lomb; CIBA Vision Corporation, a unit of Novartis; Moria, and in the contact lens business, CooperVision, Vistakon, a Johnson and Johnson company, and CIBA Vision Corporation. Our competitive position in the eye care business is enhanced by our strong presence outside the United States and our knowledge of these foreign markets, as well as technological advancement. Our larger competitors have more resources to devote to advertising and promotion, and this may negatively impact our competitive position.

Our competitors may develop technologies and products that are more effective or less costly than any of our current or future products or that could render our products obsolete or noncompetitive. Some of these competitors have substantially more resources and marketing capabilities than we do. Among other things, these consolidated companies can spread their research and development costs over much broader revenue bases than we can and can influence customer and distributor buying decisions. Our inability to produce and develop products that compete effectively against those of our competitors could result in a material reduction in sales.

### **Patents, Trademarks and Other Intellectual Property**

Patents and other proprietary rights are important to the success of our business. We likewise utilize trade secrets, know-how, continuing technological innovations and licensing opportunities to develop and maintain our competitive position. We protect our proprietary rights through a variety of methods, including confidentiality agreements and proprietary information agreements with vendors, employees, consultants and others who have access to our proprietary information.

We have rights to over 1,475 granted and issued patents and approximately 915 pending patent applications relating to aspects of the technology incorporated in many of our products. The scope and duration of our proprietary protection varies throughout the world by jurisdiction and by individual product. In particular, patents for individual products extend for varying periods of time according to the date a patent application is filed, the date a patent is granted and the term of patent protection available in the jurisdiction granting the patent. Our proprietary protection often affords us the opportunity to enhance our position in the marketplace by precluding our competitors from using or otherwise exploiting our technology.

We believe trademark protection is particularly important to the maintenance of the recognized brand names under which we market our products. The scope and duration of our trademark protection varies throughout the world, with some countries protecting trademarks only as long as the mark is used, and others requiring registration of the mark and the payment of registration fees. We own or have rights to material trademarks or trade names that we use in conjunction with the sale of our products, which include, among others, *Advanced Medical Optics* (and design), *Allervis*<sup>®</sup>, *Amadeus*, *AMO*, *AMO Pupil Smart*, *Array*, (and design), *Baerveldt*, *blink*, *blink contacts*, *Blink-n-Clean*<sup>®</sup>, *CeeOn*<sup>®</sup>, *CeeOn*

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*Edge, ClariFlex, Clean-N-Soak, ComfortPLUS<sup>®</sup>, Complete (and design), Complete MoisturePLUS, Complete Rapidcare, Consept F, Consept 1 Step, Diplomax, Endosol, GMAqua, Healon<sup>®</sup>, Healon5 (design), Healon GV<sup>®</sup>, Injector Ring LC65, Lens Plus<sup>®</sup>, MoisturePLUS, Ocupure, OptiEdge, Oxysept, Oxysept 1 Step, PhacoFlex II, AMO Prestige, (and design), Proficient, ReZoom (and design), Sensar, Sovereign, Sovereign Compact SI30NB<sup>®</sup>, SI40NB<sup>®</sup>, Stabileyes, Stylus, Tecnis, The Future in Sight, The Unfolder<sup>®</sup>, Total Care, UltraCare, Ultrazyme<sup>®</sup>, Verisyse, Vitrax, and WhiteStar (and design).* Generally, our products are marketed under one of these trademarks or brand names.

We are also a party to several license agreements relating to various of our products; however, we do not believe the loss of any one license would materially affect our business. *Amadeus* and *SurePass* are trademarks of SIS Ltd. *OptiEdge* is a trademark of Ocular Sciences.

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We believe that our patents, trademarks and other proprietary rights are important to the development and conduct of our business and the marketing of our products. As a result, we aggressively protect our intellectual property. However, we do not believe that any one of our patents or trademarks is currently of material importance in relation to our overall sales.

## **Information Available on our Website**

Our Internet address is [www.amo-inc.com](http://www.amo-inc.com). We make available on our website, free of charge, our filings made with the SEC electronically, including those on Form 10-K, Form 10-Q, and Form 8-K, and any amendments to those filings. Copies are available as soon as reasonably practicable after we have filed or furnished these documents to the SEC. Our Code of Ethics, which applies to all employees, is available on our website. Our Code of Ethics is also available in print to any stockholder who requests it from our Investor Relations department, (714) 247-8348. Any changes to the Code of Ethics or waivers granted to our chief executive officer, chief financial officer or controller by our board of directors will be publicized on our website.

## **Our Agreements with Allergan**

As a result of the spin-off, we and Allergan operate independently of each other as separate public companies. Neither we nor Allergan have any beneficial stock ownership interest in the other. In connection with the spin-off, we entered into a contribution and distribution agreement with Allergan that, together with other ancillary agreements with Allergan, have facilitated our separation from Allergan. Certain of these agreements continue to govern our relationship with Allergan subsequent to the spin-off and provide for the allocation of employee benefits, tax and other liabilities and obligations. Allergan India Private Limited is a distributor of our products in India. We have given notice that we will terminate the distribution agreement effective July 2005 and will purchase the assets of the business related to AMO products at a price which has not yet been determined. We do not expect the transaction to materially affect our financial position or liquidity.

## **Certain Factors and Trends Affecting AMO and Its Businesses**

Certain statements we made in this report and in other reports and statements released by us constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, such as comments which express our opinions about trends and factors which may impact future operating results. Disclosures that use words such as we believe, anticipate, expect and similar expressions are intended to identify forward-looking statements. Such statements are subject to certain risks and uncertainties that could cause actual results to differ materially from 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 and our proposed acquisition of VISX, Incorporated including, without limitation, the factors discussed below.

## **RISKS RELATING TO THE BUSINESS**

**WE MAY NOT SUCCESSFULLY MAKE OR INTEGRATE ACQUISITIONS OR ENTER INTO STRATEGIC ALLIANCES.** As part of our business strategy, we intend to pursue selected acquisitions and strategic alliances and partnerships. We compete with other ophthalmic surgical products and eye care companies, among others, for these opportunities and we cannot assure you that we will be able to effect strategic alliances, partnerships or acquisitions on commercially reasonable terms or at all. Even if we do enter into these transactions, we may experience:

delays in realizing the benefits we anticipate or we may not realize the benefits we anticipate at all;

difficulties in integrating any acquired companies and products into our existing business;

attrition of key personnel from acquired businesses;

costs or charges;

difficulties or delays in obtaining regulatory approvals;

higher costs of integration than we anticipated; or

unforeseen operating difficulties that require significant financial and managerial resources that would otherwise be available for the ongoing development or expansion of our existing operations.

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Consummating these transactions could also result in the incurrence of additional debt and related interest expense, as well as unforeseen contingent liabilities, all of which could have a material adverse effect on our business, financial condition and results of operations. We may also issue additional equity in connection with these transactions, which would dilute our existing shareholders.

WE CONDUCT A SIGNIFICANT AMOUNT OF OUR SALES AND OPERATIONS OUTSIDE OF THE UNITED STATES, WHICH SUBJECTS US TO ADDITIONAL BUSINESS RISKS THAT MAY CAUSE OUR PROFITABILITY TO DECLINE. Because we manufacture and sell a significant portion of our products in a number of foreign countries, our business is subject to risks associated with doing business internationally. In particular, our products are sold in over 60 countries, and our manufacturing facilities are located outside the continental United States, in Añasco, Puerto Rico; Madrid, Spain; and Hangzhou, China. In connection with the acquisition of the ophthalmic Pfizer surgical business, we acquired Pfizer's ophthalmic surgical products and certain manufacturing and research and development facilities located in Uppsala, Sweden; Groningen, Netherlands; and Bangalore, India. In 2004, on an historical basis, we derived approximately \$555 million, or 75%, of our net sales, from sales of our products outside of the United States, including 26% of our net sales in Japan. We intend to continue to pursue growth opportunities in sales internationally, which could expose us to greater risks associated with international sales and operations. Our international operations are, and will continue to be, subject to a number of risks and potential costs, including:

- unexpected changes in foreign regulatory requirements;
- differing local product preferences and product requirements;
- fluctuations in foreign currency exchange rates;
- political and economic instability;
- changes in foreign medical reimbursement and coverage policies and programs;
- diminished protection of intellectual property in some countries outside of the United States;
- trade protection measures and import or export licensing requirements;
- difficulty in staffing and managing foreign operations;
- differing labor regulations; and
- potentially negative consequences from changes in tax laws.

Any of these factors may, individually or as a group, have a material adverse effect on our business and results of operations. In addition, we are particularly susceptible to the occurrence of any of these risks in Japan due to our high concentration of sales in Japan.

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As we expand our existing international operations, we may encounter new risks. For example, as we focus on building our international sales and distribution networks in new geographic regions, we must continue to develop relationships with qualified local distributors and trading companies. If we are not successful in developing these relationships, we may not be able to grow sales in these geographic regions. These or other similar risks could adversely affect our revenue and profitability.

**WE ARE EXPOSED TO FOREIGN CURRENCY RISKS FROM OUR INTERNATIONAL OPERATIONS THAT COULD ADVERSELY AFFECT OUR FINANCIAL RESULTS.** A significant portion of our sales and operating costs are, and from time to time, a portion of our indebtedness may be, denominated in foreign currencies. We are therefore exposed to fluctuations in the exchange rates between the U.S. dollar and the currencies in which our foreign operations receive revenues and pay expenses, including debt service. Our consolidated financial results are denominated in U.S. dollars and therefore, during times of a strengthening U.S. dollar, our reported international sales and earnings will be reduced because the local currency will translate into fewer U.S. dollars. In addition, the assets and liabilities of our non-U.S. subsidiaries are translated into U.S. dollars at the exchange rates in effect at the



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balance sheet date. Revenues and expenses are translated into U.S. dollars at the weighted average exchange rate for the period. Translation adjustments arising from the use of differing exchange rates from period to period are included in Accumulated other comprehensive income in Stockholders' equity. Gains and losses resulting from foreign currency fluctuations and remeasurements relating to foreign operations deemed to be operating in U.S. dollar functional currency are included in Other, net in our consolidated statements of operations. Accordingly, changes in currency exchange rates will cause our net earnings and stockholders' equity to fluctuate.

OUR HISTORICAL FINANCIAL INFORMATION MAY NOT BE INDICATIVE OF FUTURE RESULTS. Our historical financial information prior to our separation from Allergan does not reflect what our results of operations, financial condition and cash flows would have been had we been a separate, stand-alone entity pursuing independent strategies during the periods presented. We have not made adjustments to our historical financial information for periods prior to June 29, 2002 to reflect changes that occurred in our cost structure, financing and operations as a result of our separation from Allergan. In addition, our historical financial information for periods prior to June 29, 2002 does not reflect any increased costs associated with being a publicly traded, independent company. As a result, our historical financial information is not necessarily indicative of our future results of operations, financial condition and cash flows and should not be relied upon for evaluating its business.

IF WE DO NOT INTRODUCE NEW COMMERCIALY SUCCESSFUL PRODUCTS IN A TIMELY MANNER, OUR PRODUCTS MAY BECOME OBSOLETE OVER TIME, CUSTOMERS MAY NOT BUY OUR PRODUCTS AND OUR REVENUE AND PROFITABILITY MAY DECLINE. Demand for our products may change in ways we may not anticipate because of:

evolving customer needs;

the introduction of new products and technologies;

evolving surgical practices; and

evolving industry standards.

Without the timely introduction of new commercially successful products and enhancements, our products may become obsolete over time, in which case our sales and operating results would suffer. The success of our new product offerings will depend on several factors, including our ability to:

properly identify and anticipate customer needs;

commercialize new products in a cost-effective and timely manner;

manufacture and deliver products in sufficient volumes on time;

obtain regulatory approval for such new products;

differentiate our offerings from competitors' offerings;

achieve positive clinical outcomes;

satisfy the increased demands by health care payors, providers and patients for lower-cost procedures;

innovate and develop new materials, product designs and surgical techniques; and

provide adequate medical and/or consumer education relating to new products and attract key surgeons to advocate these new products.

Moreover, innovations generally will require a substantial investment in research and development before we can determine the commercial viability of these innovations and we may not have the financial resources necessary to fund these innovations. In addition, even if we are able to successfully develop enhancements or new generations of

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our products, these enhancements or new generations of products may not produce revenue in excess of the costs of development and they may be quickly rendered obsolete by changing customer preferences or the introduction by our competitors of products embodying new technologies or features.

**WE RELY ON CERTAIN SUPPLIERS AND MANUFACTURERS FOR RAW MATERIALS AND OTHER PRODUCTS AND ARE VULNERABLE TO FLUCTUATIONS IN THE AVAILABILITY AND PRICE OF SUCH PRODUCTS AND SERVICES.** We purchase certain raw materials and other products from third-party suppliers and vendors, sometimes from limited sources. Our suppliers and vendors may not provide the raw materials or other products needed by us in the quantities requested, in a timely manner, or at a price we are willing to pay. In the event any of our third-party suppliers or vendors were to become unable or unwilling to continue to provide important raw materials and third-party products in the required volumes and quality levels or in a timely manner, we would be required to identify and obtain acceptable replacement supply sources. We may not be able to obtain alternative suppliers and vendors on a timely basis, or at all, which could result in lost sales because of our inability to manufacture products containing such raw materials or deliver products we sell from certain suppliers. In addition, we also rely on certain manufacturers for some of our products. We have historically outsourced the manufacture of our phacoemulsification equipment to third parties. If we were unable to renew our third-party manufacturing agreements, or if the manufacturers were to cease manufacturing any of these products for us for any reason, we may not be able to find alternative manufacturers on terms favorable to us, in a timely manner, or at all. If any of these events should occur, our business, financial condition and results of operations could be materially adversely affected.

**WE FACE INTENSE COMPETITION, AND OUR FAILURE TO COMPETE EFFECTIVELY COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR PROFITABILITY AND RESULTS OF OPERATIONS.** We face intense competition in the markets for our ophthalmic surgical and eye care products and these markets are subject to rapid and significant technological change. We have numerous competitors in the United States and abroad, including, among others, large companies such as Alcon, Inc., a publicly traded subsidiary of Nestle S.A.; Bausch & Lomb; CIBA Vision Corporation, a unit of Novartis; Staar Surgical; Moria; Intralase; Eyeonics; CooperVision; and Vistakon, a Johnson and Johnson company. Many of our competitors have substantially more resources and a greater marketing scale than we do. We may not be able to sustain our current levels of profitability and growth as competitive pressures, including pricing pressure from competitors, increase. In addition, if we are unable to develop and produce or market our products to effectively compete against our competitors, our operating results will materially suffer. We also compete against a large number of providers of alternative vision correction solutions, some of which may have greater financial resources than we do. For example, if LASIK technology is advanced to be able to address a wider range of refractive errors, it could reduce demand for our refractive IOLs. In addition, if contact lens use diminishes as a result of increased use of glasses, surgical correction or otherwise, our contact lens business could be materially adversely affected. New or different methods of vision correction are continually being introduced. Any of these competitive pressures could result in decreased demand for our products.

**IF WE ARE UNABLE TO PROTECT OUR INTELLECTUAL PROPERTY RIGHTS, OUR BUSINESS AND PROSPECTS MAY BE HARMED.** Our ability to compete effectively is dependent upon our ability to protect and preserve the proprietary aspects of the designs, processes, technologies and materials owned by, used by or licensed to us. We have numerous U.S. patents and corresponding foreign patents that are expected to expire by their own terms at various dates and have additional patent applications pending that may not result in issued patents. Our failure to secure these patents may limit our ability to protect the intellectual property rights that these applications were intended to cover. Although we have attempted to protect our proprietary intellectual property, technologies and processes both in the United States and in foreign countries through a combination of patent law, trade secrets and non-disclosure agreements, these may be insufficient. Competitors may be able to design around our patents to compete effectively with our products. We also may not be able to prevent third parties from using our technology without our authorization, breaching any non-disclosure agreements with us, or independently developing technology that is similar to ours. The use of our technology or similar technology by others could reduce or eliminate any competitive advantage we have developed, cause us to lose sales or otherwise harm our business. If it became necessary for us to resort to litigation to protect these rights, any proceedings could be costly and we may not prevail. Further, we may not be able to obtain patents or other protections on our future innovations. In addition, because of the differences in foreign patent and other laws concerning proprietary rights, our products may not receive the same degree of protection in foreign countries as they would in the United States. We cannot assure you that:

pending patent applications will result in issued patents;



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patents issued to or licensed by us will not be challenged by third parties; or

our patents will be found to be valid or sufficiently broad to protect our technology or provide us with a competitive advantage.

**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.** There is a substantial amount of litigation over patent and other intellectual property rights in the eye care industry and in the ophthalmic surgical products and contact lens care markets particularly. The fact that we have patents issued to us for our products does not mean that we will always be able to successfully defend our patents and proprietary rights against challenges or claims of infringement by our competitors. A successful claim of patent or other intellectual property infringement or misappropriation against us could adversely affect our growth and profitability, in some cases materially. We cannot assure you that our products do not and will not infringe issued patents or other intellectual property rights of third parties. From time to time, in the ordinary course of business, we receive notices from third parties alleging infringement or misappropriation of the patent, trademark and other intellectual property rights of third parties by us or our consumers in connection with the use of our products. We may be unaware of intellectual property rights of others that may cover some of our technology. If someone claims that our products infringe their intellectual property rights, whether or not such claims are meritorious, any resulting litigation could be costly and time consuming and would divert the attention of management and personnel from other business issues. The complexity of the technology involved and the uncertainty of intellectual property litigation increase these risks. Claims of intellectual property infringement also might require us to enter into costly royalty or license agreements (if available on acceptable terms or at all). We also may be subject to significant damages or an injunction preventing us from manufacturing, selling or using some or some aspect of our products. We may also need to redesign some of our products or processes to avoid future infringement liability. Any of these adverse consequences could have a material adverse effect on our business and profitability.

**WE MAY HAVE DIFFICULTY TRANSITIONING OUR MANUFACTURING OPERATIONS, AND OUR MANUFACTURING CAPACITY MAY NOT BE ADEQUATE TO MEET THE DEMANDS OF OUR BUSINESS.** We manufacture our products or contract with third parties to manufacture products for us. In June 2005, our manufacturing agreement with Allergan will terminate. As a result, in November 2003, we acquired a facility in Madrid, Spain, and we plan to transition products manufactured by Allergan for us to this facility as well as our Hangzhou, China facility. We also plan to transition other products to third-party suppliers. The process to transfer manufacturing of our products to a new facility or other third parties is lengthy and requires regulatory approval. We cannot assure you that we can successfully transition our manufacturing on a profitable basis, complete the regulatory approval process in a timely manner or contract with third parties on terms acceptable to us or at all. In addition, if our sales increase substantially, we may need to increase our production capacity even further. Any prolonged disruption in the operation of our manufacturing facilities or those of our third-party manufacturers could materially harm our business. We cannot assure you that if we choose to scale-up our manufacturing operations, we will be able to obtain regulatory approvals in a timely fashion, which could affect our ability to meet product demand or result in additional costs.

Through the acquisition of the Pfizer ophthalmic surgery business, we acquired three manufacturing facilities in Groningen, Netherlands, Uppsala, Sweden and Bangalore, India. We expect to incur significant capital expenditures with respect to the Uppsala, Sweden manufacturing facility during the first two years following the acquisition in order to separate the facility from existing Pfizer operations. These capital expenditures may be significantly higher than we expect. Although we have an agreement with Pfizer to assist us with the separation and related transition services, there can be no assurances that Pfizer will be able to provide the necessary services to enable us to transition and separate the Uppsala facility in the manner and in the time frame that we desire.

**WE COULD EXPERIENCE LOSSES DUE TO PRODUCT LIABILITY CLAIMS OR PRODUCT RECALLS OR CORRECTIONS.** We have in the past been, and continue to be, subject to product liability claims. In connection with our spin-off from Allergan, we assumed the defense of any litigation involving claims related to our business and agreed to indemnify Allergan for all related losses, costs and expenses. As part of our risk management policy, we have obtained third-party product liability insurance coverage. Product liability claims against us may exceed the coverage limits of our insurance policies or cause us to record a self-insured loss. A product liability claim in



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excess of applicable insurance could have a material adverse effect on our business, financial condition and results of operations. Even if any product liability loss is covered by an insurance policy, these policies have substantial retentions or deductibles that provide that we will not receive insurance proceeds until the losses incurred exceed the amount of those retentions or deductibles. To the extent that any losses are below these retentions or deductibles, we will be responsible for paying these losses. The payment of retentions or deductibles for a significant amount of claims could have a material adverse effect on our business, financial condition and results of operations.

In addition, we are subject to medical device reporting regulations that require us to report to the FDA or similar governmental authorities in other countries if our products cause or contribute to a death or serious injury or malfunction in a way that would be reasonably likely to contribute to death or serious injury if the malfunction were to recur. The FDA and similar governmental authorities in other countries have the authority to require the recall our products in the event of material deficiencies or defects in design or manufacturing. A government mandated or voluntary recall by us could occur as a result of manufacturing errors or design defects, including defects in labeling. We have undertaken voluntary recalls of our products in the past.

Any product liability claim or recall would divert managerial and financial resources and could harm our reputation with customers. We cannot assure you that we will not have product liability claims or recalls in the future or that such claims or recalls would not have a material adverse effect on our business.

**IF WE FAIL TO MAINTAIN OUR RELATIONSHIPS WITH HEALTH CARE PROVIDERS, CUSTOMERS MAY NOT BUY OUR PRODUCTS AND OUR REVENUE AND PROFITABILITY MAY DECLINE.** We market our products to numerous health care providers, including eye care professionals, hospitals, ambulatory surgical centers, corporate optometry chains and group purchasing organizations. We have developed and strive to maintain close relationships with members of each of these groups who assist in product research and development and advise us on how to satisfy the full range of surgeon and patient needs. We rely on these groups to recommend our products to their patients and to other members of their organizations. The failure of our existing products and any new products we may introduce to retain the support of these various groups could have a material adverse effect on our business, financial condition and results of operations.

**WE GENERALLY DO NOT HAVE LONG-TERM CONTRACTS WITH OUR CUSTOMERS.** We generally do not enter into long-term contracts with our customers. As a result, we are exposed to volatility in the market for our products and loss of our customers. As a result, we may not be able to maintain our level of profitability. If we are unable to market our products on terms we find acceptable, our financial condition and results of operations could suffer materially.

**OUR BUSINESS IS SUBJECT TO EXTENSIVE GOVERNMENT REGULATION.** Our products and operations are subject to extensive regulation in the United States by the FDA and various other federal and state regulatory agencies, including with respect to regulatory approval of our products and health care fraud and abuse, such as anti-kickback and physician self-referral laws and regulations. Additionally, in many foreign countries in which we market our products, we are subject to similar regulations. Compliance with these regulations is expensive and time-consuming. If we fail to comply, we may be subject to fines, injunctions and penalties that could harm our business. Product sales, introductions or modifications may be delayed or canceled as a result of U.S. or foreign regulatory processes, which could cause our sales to decline. Failure to obtain regulatory clearance or approvals of new products we develop, any limitations imposed by regulatory agencies on new product use or the costs of obtaining regulatory clearance or approvals could have a material adverse effect on our business, financial condition and results of operations. In addition, if we, our subcontractors or third-party manufacturers or suppliers of products we distribute fail to comply with applicable manufacturing regulations, our business could be harmed.

Health care initiatives and other cost-containment pressures could cause us to sell our products at lower prices, resulting in less revenue to us. In the United States, a significant percentage of the patients who receive our intraocular lenses are covered by the federal Medicare program. Reductions in Medicare reimbursement rates and the implementation of other price controls could adversely affect our revenues and financial condition. In addition, changes in existing regulatory requirements or adoption of new requirements could hurt our business, financial condition and results of operations.

OUR BUSINESS IS SUBJECT TO ENVIRONMENTAL REGULATIONS. Our facilities and operations are subject to federal, state and local environmental and occupational health and safety requirements of the United



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States and foreign countries, including those relating to discharges of substances to the air, water and land, the handling, storage and disposal of wastes and the cleanup of properties affected by pollutants. Failure to maintain compliance with these regulations could have a material adverse effect on our business or financial condition. The facilities we obtained in connection with the acquisition of the Pfizer ophthalmic surgical business are also subject to such requirements and risks.

In the future, federal, state or local governments in the United States or foreign countries could enact new or more stringent laws or issue new or more stringent regulations concerning environmental and worker health and safety matters that could affect our operations. Also, in the future, contamination may be found to exist at our current or former facilities or off-site locations where we have sent wastes. We could be held liable for such newly discovered contamination which could have a material adverse effect on our business or financial condition. In addition, changes in environmental and worker health and safety requirements could have a material adverse effect on our business or financial condition.

IF WE FAIL TO ATTRACT, HIRE AND RETAIN QUALIFIED PERSONNEL, WE MAY NOT BE ABLE TO DESIGN, DEVELOP, MARKET OR SELL OUR PRODUCTS OR SUCCESSFULLY MANAGE OUR BUSINESS. Our ability to attract new customers, retain existing customers and pursue our strategic objectives depends on the continued services of our current management, sales, product development and technical personnel and our ability to identify, attract, train and retain similar personnel. Competition for top management personnel is intense and we may not be able to recruit and retain the personnel we need. The loss of any one of our management personnel, or our inability to identify, attract, retain and integrate additional qualified management personnel, could make it difficult for us to manage our business successfully and pursue our strategic objectives. Similarly, competition for skilled sales, product development and technical personnel is intense and we may not be able to recruit and retain the personnel we need. The loss of services of a number of key sales, product development and technical personnel, or our inability to hire new personnel with the requisite skills, could restrict our ability to develop new products or enhance existing products in a timely manner, sell products to our customers or manage our business effectively.

We may not be able to hire or retain qualified personnel if we are unable to offer competitive salaries and benefits. If our stock does not perform well, we may have to increase our salaries and benefits, which would increase our expenses and reduce our profitability.

WE MAY BE REQUIRED TO SATISFY CERTAIN INDEMNIFICATION OBLIGATIONS TO ALLERGAN, AND WE MAY NOT BE ABLE TO COLLECT ON INDEMNIFICATION RIGHTS FROM ALLERGAN. Under the terms of our contribution and distribution agreement with Allergan, we and Allergan have each agreed to indemnify each other from and after our spin-off with respect to the debt, liabilities and obligations retained by the respective companies. These indemnification obligations could be significant. The ability to satisfy these indemnities, if called upon to do so, will depend upon the future financial strength of each of the respective companies. We cannot determine whether we will have to indemnify Allergan for any substantial obligations, and we may not have control over the settlement of certain claims and lawsuits that may require partial indemnification by us. We also cannot assure you that, if Allergan is required to indemnify it for any substantial obligations, Allergan will have the ability to satisfy those obligations.

WE MAY BE RESPONSIBLE FOR FEDERAL INCOME TAX LIABILITIES THAT RELATE TO THE DISTRIBUTION OF OUR COMMON STOCK BY ALLERGAN. Allergan has received a ruling from the Internal Revenue Service to the effect that the spin-off qualified as a tax-free transaction. If either we or Allergan breach representations to each other or to the Internal Revenue Service, or if we or Allergan take or fail to take, as the case may be, actions that result in the spin-off failing to meet the requirements of a tax-free spin-off pursuant to Section 355 of the Internal Revenue Code, the party in breach will indemnify the other party for any and all resulting taxes. If we were required to pay any of the potential taxes described above, the payment would have a material adverse effect on our financial position.

WE HAVE A SIGNIFICANT AMOUNT OF DEBT WHICH CONTAINS COVENANTS THAT MAY LIMIT OUR ACTIVITIES. This level of debt could limit cash flows available for working capital, capital expenditures, acquisitions and other corporate purposes, could limit our ability to obtain additional financing and could limit our flexibility to react to competitive or other changes in the industry, and to economic conditions generally. Our ability to comply with loan covenants and to repay or refinance our

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indebtedness will depend upon our future operating performance, which will be affected by general economic, financial, competitive, legislative, regulatory and other factors beyond our control.

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DESPITE OUR CURRENT LEVEL OF INDEBTEDNESS, WE MAY INCUR SUBSTANTIALLY MORE DEBT, WHICH COULD FURTHER EXACERBATE THE RISKS ASSOCIATED WITH OUR SUBSTANTIAL INDEBTEDNESS. Although certain of our debt agreements contain restrictions on the incurrence of additional indebtedness, these restrictions are subject to a number of qualifications and exceptions, and the indebtedness incurred while remaining in compliance with these restrictions could be substantial. Also, these restrictions do not prevent us from incurring obligations that do not constitute indebtedness as defined in the relevant agreement. If new debt is added to our current debt levels, the related risks that we now face could intensify.

RECENT CHANGES IN THE ACCOUNTING TREATMENT OF STOCK OPTIONS COULD HAVE A NEGATIVE IMPACT ON OUR FINANCIAL STATEMENTS AND CAUSE OUR STOCK PRICE TO DECLINE. On December 16, 2004, the Financial Accounting Standards Board (FASB) issued FASB Statement No. 123(R), Share-Based Payment, or FAS 123(R), which includes proposed rule changes requiring companies to expense the fair value of employee stock options and other forms of stock-based compensation. Currently, we include the fair market value of employee stock options on a pro forma basis in the notes to our annual financial statements in accordance with accounting principles generally accepted in the United States, but do not record a charge for employee stock option expense in the reported financial statements. Once we are required to comply with FAS 123(R) as of the beginning of the third quarter of 2005, our reported earnings are expected to decrease. Such a decrease may lead to a decline in our stock price.

OUR STOCKHOLDER RIGHTS PLAN, CERTIFICATE OF INCORPORATION AND BYLAWS, AS WELL AS PROVISIONS OF DELAWARE LAW, COULD MAKE IT DIFFICULT FOR A THIRD PARTY TO ACQUIRE US. We have a stockholder rights plan that may have the effect of discouraging unsolicited takeover proposals. The rights issued under the stockholder rights plan would cause substantial dilution to a person or group that attempts to acquire us on terms not approved in advance by our board of directors. In addition, Delaware corporate law and our certificate of incorporation and bylaws contain provisions that could delay, deter or prevent a change in control of our company or our management. These provisions could also discourage proxy contests and make it more difficult for our stockholders to elect directors and take other corporate actions without the concurrence of our management or board of directors. These provisions:

authorize our board of directors to issue blank check preferred stock, which is preferred stock that can be created and issued by our board of directors, without stockholder approval, with rights senior to those of common stock;

provide for a staggered board of directors and three-year terms for directors, so that no more than one-third of our directors could be replaced at any annual meeting;

provide that directors may be removed only for cause;

provide that stockholder action may be taken only at a special or regular meeting and not by written consent;

provide for super-majority voting requirements for some provisions of our certificate of incorporation; and

establish advance notice requirements for submitting nominations for election to the our board of directors and for proposing matters that can be acted upon by stockholders at a meeting.

We are also subject to anti-takeover provisions under Delaware law, which could also delay or prevent a change of control. Together, these provisions of our certificate of incorporation and bylaws, Delaware law and our stockholder rights plan may discourage transactions that otherwise could provide for the payment of a premium over prevailing market prices of our common stock and, possibly, our notes, and also could limit the price that investors are willing to pay in the future for shares of our common stock and the notes.



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**RISKS RELATING TO THE MERGER WITH VISX, INCORPORATED**

THE ISSUANCE OF SHARES OF AMO COMMON STOCK TO VISX STOCKHOLDERS IN THE MERGER WILL SUBSTANTIALLY REDUCE THE PERCENTAGE INTERESTS OF AMO STOCKHOLDERS. If the merger is completed, we expect that, based on data as of January 26, 2005, approximately 27.6 million shares of AMO common stock will be issued to VISX stockholders and, upon exercise of assumed options, up to approximately 1.6 million shares will be issued to holders of assumed options and phantom units. Based on the number of shares of AMO and VISX common stock outstanding on January 26, 2005, VISX stockholders before the merger will own, in the aggregate, approximately 41.5% of the fully diluted shares of AMO common stock immediately after the merger. The issuance of approximately up to 29.2 million shares of AMO common stock to VISX stockholders and holders of assumed options and phantom units will cause a significant reduction in the relative percentage interest of current AMO stockholders in earnings, voting, liquidation value and book and market value. In addition, under certain circumstances described more fully in the following risk factor, the amount of AMO common stock issuable for each share of VISX common stock may be increased, and the amount of cash payable for each share of VISX common stock may be decreased. In the event of any such adjustment, VISX stockholders as a whole will hold a larger percentage of the fully diluted AMO common stock immediately after giving effect to the merger.

THE MERGER CONSIDERATION MAY BE ADJUSTED IN ORDER TO QUALIFY THE MERGER AS A REORGANIZATION WITHIN THE MEANING OF SECTION 368(A) OF THE INTERNAL REVENUE CODE. We intend for the merger to qualify as a reorganization within the meaning of Section 368(a) of the Internal Revenue Code. However, if neither Skadden, Arps, Slate, Meagher & Flom LLP, counsel to AMO, nor Wilson Sonsini Goodrich & Rosati, Professional Corporation, counsel to VISX, is able to render an opinion at the completion of the merger that the merger qualifies as a reorganization within the meaning of Section 368(a) of the Internal Revenue Code, based on the negotiated mix of cash and stock consideration, then the amount of the cash merger consideration will be reduced and the amount of the stock merger consideration will be increased, in each case to the minimum extent necessary to enable either counsel to render this opinion at the completion of the merger. As a result of this adjustment of the merger consideration, VISX stockholders could receive a different mix of cash and AMO common stock for each share of VISX common stock than is currently anticipated.

THE PRICE OF AMO COMMON STOCK MAY DECLINE, WHICH WOULD DECREASE THE VALUE OF THE STOCK PORTION OF THE MERGER CONSIDERATION TO BE RECEIVED BY VISX STOCKHOLDERS IN THE MERGER AND MAY PREVENT THE COMPLETION OF THE MERGER. The price of AMO common stock might decline from the \$41.70 price per share at the close of trading on November 8, 2004, the last full trading day prior to the public announcement of the proposed merger. Accordingly, if the price of AMO common stock declines prior to the completion of the merger, the value of the stock portion of the merger consideration to be received by VISX stockholders in the merger will decrease as compared to the value on the date the merger was announced. If on the closing date of the merger AMO common stock is trading below the price at which AMO and VISX counsel is able to render the opinion discussed in the immediately preceding risk factor, then the amount of the cash merger consideration will be reduced and the amount of the stock merger consideration will be increased, in each case to the minimum extent necessary for either of AMO or VISX counsel to be able to render such opinion. If the increase in stock merger consideration results in the aggregate stock merger consideration issuable to the VISX stockholders in the merger, to holders of VISX stock options assumed in the merger and to the holders of units of phantom stock accounts assumed in the merger constituting more than 44.9% of the number of outstanding shares of AMO common stock immediately following the completion of the merger, then the walk away right would be triggered. We currently estimate that the stock merger consideration would be increased to a level that would trigger this walk away right if the trading price of AMO common stock declined to approximately \$17.75.

EVEN THOUGH AMO AND VISX HAVE OBTAINED THE REGULATORY APPROVALS REQUIRED TO COMPLETE THE MERGER, GOVERNMENTAL AUTHORITIES COULD STILL SEEK TO BLOCK OR CHALLENGE THE MERGER. The merger is subject to review by the Antitrust Division of the Department of Justice and the FTC under the Hart-Scott-Rodino Antitrust Improvements Act of 1976 (HSR Act). Under the HSR Act, AMO and VISX are required to make pre-merger notification filings and to await the expiration or early termination of the statutory waiting period prior to completing the merger. The merger is also subject to review by certain other governmental authorities under the antitrust laws of various other jurisdictions where VISX conducts business. We have made all required regulatory filings, the applicable waiting periods have expired and we have therefore obtained all regulatory clearances, consents and approvals required to complete with the merger. However,



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after the statutory waiting periods have expired, and even after completion of the merger, governmental authorities could seek to block or challenge the merger as they deem necessary or desirable in the public interest. In addition, in some jurisdictions, a competitor, customer or other third party could initiate a private action under the antitrust laws challenging or seeking to enjoin the merger, before or after it is completed. AMO, VISX or the combined company may not prevail, or may incur significant costs, in defending or settling any action under the antitrust laws.

AMO WILL HAVE MORE INDEBTEDNESS AFTER THE MERGER, WHICH COULD ADVERSELY AFFECT ITS CASH FLOWS AND BUSINESS. In order to complete the merger, AMO anticipates arranging for and funding at least \$200 million of new financing. Proceeds from the financing will be used to fund the cash portion of the consideration paid to VISX stockholders. AMO debt outstanding as of December 31, 2004 was approximately \$552.6 million. As a result of the increase in debt, demands on AMO cash resources may increase after the completion of the merger. The increased levels of debt could, among other things:

require AMO to dedicate a substantial portion of its cash flow from operations to payments on its debt, thereby reducing funds available for working capital, capital expenditures, acquisitions and other purposes;

increase AMO's vulnerability to, and limit flexibility in planning for, adverse economic and industry conditions;

affect AMO's credit rating;

limit AMO's ability to obtain additional financing to fund future working capital, capital expenditures, additional acquisitions and other general corporate requirements;

create competitive disadvantages compared to other companies with less indebtedness; and

limit AMO's ability to apply proceeds from an offering or asset sale to purposes other than the repayment of debt.

ALTHOUGH AMO EXPECTS THAT THE MERGER WILL RESULT IN BENEFITS TO THE COMBINED COMPANY, THE COMBINED COMPANY MAY NOT REALIZE THOSE BENEFITS BECAUSE OF INTEGRATION AND OTHER CHALLENGES. AMO's ability to realize the anticipated benefits of the merger will depend, in part, on the ability of AMO to integrate the business of VISX with the business of AMO. The combination of two independent companies is a complex, costly and time-consuming process. This process may disrupt the business of either or both of the companies, and may not result in the full benefits expected by AMO. The difficulties of combining the operations of the companies include, among others:

coordinating marketing functions;

unanticipated issues in integrating information, communications and other systems;

unanticipated incompatibility of purchasing, logistics, marketing and administration methods;

retaining key employees;

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consolidating corporate and administrative infrastructures;

the diversion of management's attention from ongoing business concerns; and

coordinating geographically separate organizations.

We cannot assure you that the combination of VISX with AMO will result in the realization of the full benefits anticipated from the merger.

**IF THE PROPOSED MERGER IS NOT COMPLETED, AMO WILL HAVE INCURRED SUBSTANTIAL COSTS THAT MAY ADVERSELY AFFECT AMO'S FINANCIAL RESULTS AND OPERATIONS AND THE MARKET PRICE OF AMO COMMON STOCK. AMO has incurred and will incur substantial costs in connection**



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with the proposed merger. These costs are primarily associated with the fees of attorneys, accountants and AMO's financial advisors. In addition, AMO has diverted significant management resources in an effort to complete the merger and is subject to restrictions contained in the merger agreement on the conduct of its business. If the merger is not completed, AMO will have incurred significant costs, including the diversion of management resources, for which it will have received little or no benefit. Also, if the merger is not completed under certain circumstances specified in the merger agreement, AMO may be required to pay VISX expenses in the amount of \$8 million or a break-up fee of \$45 million.

In addition, if the merger is not completed, AMO may experience negative reactions from the financial markets and AMO's collaborative partners, customers and employees. Each of these factors may adversely affect the trading price of AMO common stock and AMO's financial results and operations.

PROVISIONS OF THE MERGER AGREEMENT MAY DETER ALTERNATIVE BUSINESS COMBINATIONS AND COULD NEGATIVELY IMPACT THE STOCK PRICE OF AMO IF THE MERGER AGREEMENT IS TERMINATED IN CERTAIN CIRCUMSTANCES. Restrictions in the merger agreement on solicitation generally prohibit AMO from soliciting any acquisition proposal or offer for a merger or business combination with any other party, including a proposal that might be advantageous to the stockholders of AMO when compared to the terms and conditions of the proposed merger. In addition, if the merger is not completed under certain circumstances specified in the merger agreement, AMO may be required to pay VISX's expenses in the amount of \$8 million or a break-up fee of \$45 million. These provisions may deter third parties from proposing or pursuing alternative business combinations that might result in greater value to AMO stockholders than the merger. In the event the merger is terminated by AMO or VISX in circumstances that obligate either party to pay the expenses or break-up fee to the other party, including where either party terminates the merger agreement because the other party's board of directors withdraws its support of the merger, AMO's stock price may decline.

## **Item 2. Properties**

Our principal executive offices and research facilities are located in Santa Ana, California, in a facility subleased by us through July 2015. We conduct our global operations in facilities that we own or lease. Material facilities include administrative facilities in Australia, Canada, France, Germany, Hong Kong, Ireland, Italy, Spain and the United Kingdom. We also have two facilities in Japan, one used for administration and research and development and the other used for warehousing. We lease all of these facilities. In addition, we operate six manufacturing facilities: one in Añasco, Puerto Rico, where we lease the land and the facility, one in Madrid, Spain, where we own the land and the facility, one in Hangzhou, China, where we own the facility but lease the land, one in Uppsala, Sweden, where we own the land and the facility, one in Groningen, Netherlands, where we own the land and the facility, and one in Bangalore, India, where we own the land and the facility. We believe these facilities are adequate for the current needs of our business.

## **Item 3. Legal Proceedings**

On December 3, 2003, we filed a complaint in the U.S. District Court for the District of Delaware against Alcon, Inc. and Alcon Laboratories, Inc. for infringement of U.S. Patent Nos. 5,700,240 and 6,059,765. We alleged that Alcon's Infiniti and Series 2000 Legacy phacoemulsification machines infringe the patents. We are seeking damages and a permanent injunction. Discovery has concluded, a hearing was held on patent claims construction and multiple dispositive motions, and trial date of April 25, 2005 has been set.

On January 28, 2004, Alcon Manufacturing, Ltd. filed a complaint against us and Allergan, Inc. in the U.S. District Court for the Northern District of Texas, Fort Worth Division, for infringement of U.S. Patent Nos. 4,832,685 and 4,935,005 (Haines Patents). Alcon alleged that our *Prestige* and *Sovereign* phacoemulsification systems and replacement cassettes infringe the patents. Alcon is seeking damages and a permanent

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injunction. Discovery has commenced, however, Alcon has requested that the case be stayed in Texas while it seeks re-examination by the U.S.P.T.O. on the Haines Patents in light of another patent we allege invalidates the Haines Patents.

On January 4, 2005, Dr. James Nielsen filed a complaint against us and Allergan, Inc. in the U.S. District Court of the Northern District of Texas, Dallas Division, for infringement of U.S. Patent No. 5,158,572. Dr. Nielsen alleges that our *Array* multifocal intraocular lens infringes the patent. He is seeking damages and a permanent injunction.

While we are involved from time to time in litigation arising in the ordinary course of business, including product liability claims, we are not currently aware of any other actions against us or Allergan relating to the optical medical device

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business that we believe would have a material adverse effect on our business, financial condition, results of operations or cash flows. We may be subject to future litigation and infringement claims, which could cause us to incur significant expenses or prevent us from selling our products. We operate in an industry susceptible to significant product liability claims. Product liability claims may be asserted against us in the future arising out of events not known to us at the present time. Under the terms of the contribution and distribution agreement effecting our spin-off, Allergan agreed to assume responsibility for, and to indemnify us against, all current and future litigation relating to its retained businesses and we agreed to assume responsibility for, and to indemnify Allergan against, all current and future litigation related to the optical medical device business.

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

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

**PART II****Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities**

*Dividends.* We have never declared or paid any cash dividends on our common stock or any of our securities. We do not expect to pay cash dividends on our capital stock in the foreseeable future. We intend to retain our future earnings to continue to fund the development and growth of our business as well as repay long-term debt. In addition, our amended and restated senior credit facility prohibits us from paying cash dividends.

*Market Information.* The following table shows the quarterly price range of our common stock during the periods listed.

<u>Calendar Quarter</u>	<u>2004</u>		<u>2003</u>	
	<u>Low</u>	<u>High</u>	<u>Low</u>	<u>High</u>
First	\$ 20.04	\$ 24.73	\$ 11.30	\$ 13.65
Second	23.90	42.89	12.90	17.65
Third	34.84	42.67	15.26	18.91
Fourth	35.77	43.69	17.21	20.67

Our common stock is listed on the New York Stock Exchange and is traded under the symbol AVO. The closing price of our common stock was \$37.95 on February 28, 2005.

The approximate number of stockholders of record was 4,515 as of February 28, 2005.

*Recent Sales of Unregistered Securities.* During the quarter ended December 31, 2004, the Company issued an aggregate of 260,382 shares of common stock to a limited number of holders of the Company's 3 1/2% Convertible Senior Subordinated Notes due 2023 (the 3 1/2% convertible notes) in exchange for approximately \$4.8 million aggregate principal amount 3 1/2% convertible notes in privately negotiated transactions. The issuance of the shares of common stock was made in reliance on Section 3(a)(9) of the Securities Act of 1933, as amended.

*Purchases of Equity Securities by the Issuer.* The following sets forth the amount of 3 1/2% convertible notes acquired by AMO during the quarter ended December 31, 2004:

**ISSUER PURCHASES OF EQUITY SECURITIES**

<u>Period</u>	<u>Total Number of Shares or Units Purchased</u>	<u>Average Price Paid per Share or Unit</u>	<u>Total Number of Shares or Units Purchased as Part of Publicly Announced Plans or Programs</u>	<u>Maximum Number (or Approximate Dollar Value) of Shares or Units that May Yet Be Purchased Under the Plans or Programs</u>
September 25, 2004 - October 29, 2004	None		None	None
October 30, 2004 - November 25, 2004	\$3,000,000 in principal amount	48.69 shares of common stock for each \$1,000 principal amount of notes and accrued and unpaid interest thereon	None	None
November 26, 2004 - December 31, 2004	\$1,842,000 in principal amount	48.69 shares of common stock for each \$1,000 principal amount of notes and accrued and unpaid interest thereon	None	None

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**Item 6. Selected Financial Data**

The following table sets forth selected financial data as of and for each of the years in the five-year period ended December 31, 2004, which has been derived from our audited consolidated financial statements. After December 31, 2001, goodwill is no longer amortized. Goodwill amortization was \$9.0 million and \$9.3 million in the years ended December 31, 2001 and 2000, respectively.

The selected financial data may not be indicative of the results of operations or financial position that we would have obtained if we had been an independent company during all pre-spin-off periods presented.

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No earnings per share data is presented for each of the years in the three-year period ended December 31, 2002 as our earnings were a part of Allergan's earnings through the close of business on June 28, 2002.

	For the Year Ended December 31,				
	2004(a)	2003	2002	2001	2000
	(in thousands, except per share data)				
<b>Statement of Operations:</b>					
Net sales	\$ 742,099	\$ 601,453	\$ 538,087	\$ 543,095	\$ 570,573
Cost of sales	306,164	227,811	204,338	212,090	231,426
<b>Gross profit</b>	<b>435,935</b>	<b>373,642</b>	<b>333,749</b>	<b>331,005</b>	<b>339,147</b>
Selling, general and administrative	329,197	276,695	235,977	222,885	241,047
Research and development	45,616	37,413	29,917	28,990	29,878
In-process research and development	28,100				
Restructuring/impairment (reversal)					(2,237)
<b>Operating income</b>	<b>33,022</b>	<b>59,534</b>	<b>67,855</b>	<b>79,130</b>	<b>70,459</b>
Interest expense	26,933	24,224	13,764	3,302	3,625
Loss (gain) on investments, net			3,935	793	(231)
Unrealized loss (gain) on derivative instruments	403	246	3,199	(1,294)	
Loss due to exchange of 3 1/2% Convertible Senior Subordinated Notes due 2023	116,282				
Other, net	10,620	17,802	2,385	385	(1,135)
<b>Earnings (loss) before income taxes</b>	<b>(121,216)</b>	<b>17,262</b>	<b>44,572</b>	<b>75,944</b>	<b>68,200</b>
Provision for income taxes	8,154	6,905	18,662	20,594	19,020
<b>Earnings (loss) before cumulative effect of change in accounting principle</b>	<b>(129,370)</b>	<b>10,357</b>	<b>25,910</b>	<b>55,350</b>	<b>49,180</b>
Cumulative effect of change in accounting principle, net of \$160 of tax				(391)	
<b>Net earnings (loss)</b>	<b>\$ (129,370)</b>	<b>\$ 10,357</b>	<b>\$ 25,910</b>	<b>\$ 54,959</b>	<b>\$ 49,180</b>
<b>Basic earnings (loss) per share</b>	<b>\$ (3.89)</b>	<b>\$ 0.36</b>			
<b>Diluted earnings (loss) per share</b>	<b>\$ (3.89)</b>	<b>\$ 0.35</b>			

(a) Includes results of the acquired Pfizer Inc. Surgical Ophthalmic Business since June 26, 2004 (date of acquisition).

	As of December 31,				
	2004	2003	2002	2001	2000
	(in thousands)				
<b>Balance Sheet Data:</b>					
Cash and equivalents	\$ 49,455	\$ 46,104	\$ 80,578	\$ 6,957	\$ 12,641
Current assets	376,825	252,492	274,494	210,552	228,942

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Total assets	1,076,534	461,345	463,206	377,466	404,655
Current liabilities	193,923	115,301	108,204	85,551	87,165
Long term debt, net of current portion	550,643	233,611	277,559	75,809	100,364

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

*The following discussion and analysis presents the factors that had a material effect on AMO's cash flows and results of operations during each of the three years in the period ended December 31, 2004, and the Company's financial position at that date. Except for the historical information contained herein, the following discussion contains forward-looking statements that involve risk and uncertainties. Our actual results may differ significantly from the results discussed in the forward-looking statements. Factors that might cause such differences include, but are not limited to, those discussed in the subsection entitled Certain Factors and Trends Affecting AMO and Its Businesses. This discussion and analysis should be read in conjunction with the historical consolidated financial statements of AMO and related notes thereto included elsewhere in this Form 10-K.*

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### Overview

We are a global leader in the development, manufacture and marketing of medical devices for the eye and contact lens care products. Our products in the ophthalmic surgical market include intraocular lenses, phacoemulsification systems, viscoelastics and surgical packs used in cataract surgery, and microkeratomes used in refractive surgery. Our eye care products include disinfecting solutions to destroy harmful microorganisms in and on the surface of contact lenses, daily cleaners to remove undesirable film and deposits from contact lenses, enzymatic cleaners to remove protein deposits from contact lenses and lens rewetting drops to provide added wearing comfort. Our eye care products also include contact lenses, beginning in 2004.

We have operations in approximately 20 countries and sell our products in approximately 60 countries and have organized our operations into four regions:

Americas (North and South America);

Europe, Africa and Middle East;

Japan; and

Asia Pacific (excluding Japan, but including Australia and New Zealand).

### *Pending Acquisition of VISX, Incorporated*

On November 9, 2004, we entered into an agreement with VISX, Incorporated (VISX), the global leader in laser vision correction, to acquire VISX for a combination of cash and stock with an estimated value of approximately \$1.3 billion on the announcement date. VISX manufactures excimer laser systems, associated diagnostic devices, and treatment cards. Under the terms of the definitive agreement, VISX stockholders are expected to receive 0.552 shares of our common stock and \$3.50 in cash for every share of VISX common stock they own. The transaction is expected to close during the second quarter of 2005. For a description of the risks related to this transaction, see Risks Relating to the Merger with VISX, Incorporated beginning on page 22.

### *Acquisition of Pfizer Inc. Surgical Ophthalmic Business*

On June 26, 2004, we completed the acquisition of the Pfizer Inc. surgical ophthalmic business for \$450 million in cash (Acquisition). We acquired ophthalmic surgical products and certain manufacturing and research and development facilities located in Uppsala, Sweden, Groningen, Netherlands and Bangalore, India. The products acquired include the *Healon* line of viscoelastic products used in ocular surgery, the *CeeOn* and *Tecnis* intraocular lenses and the *Baerveldt* glaucoma shunt. These assets generated sales of approximately \$150 million in 2003.



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The Acquisition has been accounted for as a purchase business combination. Under the purchase method of accounting, the assets acquired and liabilities assumed are recorded at the date of acquisition, at their respective fair values. Our reported financial position and results of operations after June 26, 2004 reflect these values. The impact of purchase accounting resulted in significant charges in the year ended December 31, 2004, including an in-process research and development charge of \$28.1 million and incremental cost of sales of \$28.1 million from the sale of acquired inventory adjusted to fair value. During the year, we also incurred other acquisition-related charges totaling approximately \$11.6 million as we integrated the Pfizer surgical ophthalmic business and eliminated duplicative functions.

### **Separation from Allergan**

Allergan spun-off its existing optical medical device business by contributing all of the assets related to the two business lines that comprise the optical medical device business to us and distributing all of our outstanding shares of common stock to its stockholders. We had no material assets, liabilities or activities as a separate corporate entity until Allergan's contribution to us of the optical medical device business. The contribution of assets and distribution to Allergan stockholders was completed on June 29, 2002. As a result of the spin-off, we are an independent public company and Allergan no longer maintains any stock ownership in us.

Allergan did not account for our business on the basis of separate legal entities, subsidiaries, divisions or segments. The accompanying consolidated financial statement for the year ended December 31, 2002 (through June 28, 2002) includes those

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revenues and expenses directly attributable to our operations and allocations of certain Allergan corporate expenses. These amounts have been allocated on a basis that was considered by Allergan management to reflect most fairly or reasonably the utilization of the services provided to us or the benefit obtained by us. All material intercompany balances have been eliminated. The financial information included herein does not necessarily reflect what the results of our operations would have been had we operated as a stand-alone public entity during the pre-spin-off period presented, and may not be indicative of our future operations.

Prior to the spin-off, we participated in various Allergan administered functions including shared services surrounding selling, general and administrative expenses, retirement and other post-retirement benefit plans, income taxes and cash management. Our allocated portion of the expenses for these services are included in selling, general and administrative expenses in our consolidated statement of operations. For the year ended December 31, 2002 (through June 28, 2002), these allocated expenses were \$23.2 million.

Prior to the spin-off, our income had been included in consolidated income tax returns filed by Allergan, and most of the related income taxes had been paid by Allergan. Allergan had managed its tax position for the benefit of its entire portfolio of businesses. Allergan's tax methodologies and elections are not necessarily reflective of the tax methodologies and elections that we would have followed or follow as a stand-alone company. Our income tax expense has been recorded as if we filed tax returns separate from Allergan.

Prior to the spin-off, we entered into several agreements with Allergan in connection with, among other things, transitional services, employee matters, manufacturing and tax sharing.

The transitional services agreement set forth charges generally intended to allow Allergan to fully recover the allocated costs of providing certain services, plus all out-of-pocket costs and expenses, except that we paid to Allergan a commission related to our products that were sold by them during the transition period. We recovered costs from Allergan in a similar manner for services provided by us. All transitional services provided under this agreement have terminated.

Under the manufacturing agreement, Allergan manufactures certain of our eye care products and *VITRAX* viscoelastics for a period of up to three years from the date of the spin-off. We purchase these products from Allergan at a price equal to Allergan's fully allocated costs plus 10%. During 2004, 2003 and 2002 (subsequent to the spin-off), we purchased \$89.3 million, \$77.0 million and \$31.8 million, respectively, of product from Allergan. On an annual basis, a pricing "true up" calculation is to be performed during the first calendar quarter. This "true up" calculation is based upon the actual volume of products shipped by Allergan to us during the preceding year versus the forecasted volume submitted by us that was used to calculate the invoiced prices. During the year, we periodically review the volume of purchases and accrue for estimated shortfalls, if any. In March 2004, we made a payment of \$0.2 million to Allergan based upon the "true up" calculation for the year ended December 31, 2003. In March 2003, we received a payment of \$0.6 million from Allergan based upon the "true up" calculation for the period subsequent to the spin-off through December 31, 2002. These payments have been recorded as an increase/decrease to cost of sales in the accompanying consolidated statements of operations. We are currently transitioning to our own manufacturing facilities. If we are unable to obtain regulatory approvals for new facilities or locate and obtain regulatory approvals for third party manufacturers to produce our products in a timely fashion, our business may be negatively impacted.

The tax sharing agreement governs Allergan's and our respective rights, responsibilities and obligations with respect to taxes for any tax period ending before, on or after the spin-off. Generally, Allergan is liable for all pre-spin-off taxes except for pre-spin-off taxes attributable to our business for 2002. In addition, the tax sharing agreement provides that Allergan is liable for taxes that are incurred as a result of restructuring activities undertaken to effectuate the spin-off.

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We and Allergan have made representations to each other and to the Internal Revenue Service in connection with the private letter ruling that Allergan has received regarding the tax-free nature of the spin-off of our common stock by Allergan to its stockholders. If either we or Allergan breach our representations to each other or to the Internal Revenue Service, or if we or Allergan take or fail to take, as the case may be, actions that result in the spin-off failing to meet the requirements of a tax-free spin-off pursuant to Section 355 of the Internal Revenue Code, the party in breach will indemnify the other party for any and all resulting taxes. As two years have passed since the spin-off, the likelihood that we will be liable for any taxes resulting from a determination by the Internal Revenue Service that the spin-off was not of a tax-free nature is considered remote. However, in the unlikely event we are found to have breached our representations to Allergan or to the Internal Revenue Service in connection with the private letter ruling, we may be liable for the resulting taxes. We do not believe such amount will exceed \$200.0 million.

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### **Critical Accounting Policies and Estimates**

#### *Revenue Recognition and Accounts Receivable*

Revenue is realized or realizable and earned when persuasive evidence of an arrangement exists, delivery has occurred, the price to the buyer is determinable and collectibility is reasonably assured. We record revenue from product sales when title and risk of ownership has been transferred to the customer, which is typically upon delivery to the customer, with the exception of intraocular lenses distributed on a consignment basis, which is upon notification of implantation in a patient.

We generally permit returns of product if such product is returned in a timely matter, in good condition, and through the normal channels of distribution. Return policies in certain international markets can be more stringent and are based on the terms of contractual agreements with the customers. Allowances for returns are provided for based upon an analysis of our historical patterns of returns matched against the sales from which they originated. To date, historical product returns have been within our estimates.

When we recognize revenue from the sale of our products, certain allowances known and estimable at time of sale are recorded as a reduction to sales. These items include cash discounts, allowances and rebates. These items are reflected as a reduction to accounts receivable to the extent the customer will or is expected to reduce its payment on the related invoice amounts. In addition, certain items such as rebates provided to customers that meet certain buying targets are paid to the customer subsequent to customer payment. Thus, such amounts are recorded as accrued liabilities. These provisions are estimated based on historical payment experience, historical relationship to revenues and estimated customer inventory levels. If the historical data and inventory estimates used to calculate these provisions do not properly reflect future activity, our financial position, results of operations and cash flows could be impacted. To date, historical sales allowances have been within our estimates.

The allowance for doubtful accounts is determined by analyzing specific customer accounts and assessing the risk of uncollectibility based on insolvency, disputes or other collection issues. In addition, we routinely analyze the different aging categories and establish allowances based on the length of time receivables are past due.

#### *Inventories*

Inventories are valued at the lower of first-in, first-out cost or market. On a regular basis, we evaluate inventory balances for excess quantities and obsolescence by analyzing estimated demand, inventory on hand, sales levels and other information. Based on these evaluations, inventory balances are reduced, if necessary.

#### *Goodwill and Long-Lived Assets*

On January 1, 2002, we adopted Statement of Financial Accounting Standards No. 142, *Goodwill and Other Intangible Assets*, whereby goodwill is no longer amortized, but instead is subject to a periodic impairment review performed during the second quarter of each fiscal year.

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In a business combination, goodwill is allocated to our various reporting units, which are the same as our reportable operating segments based on relative fair value of the asset acquired and liabilities assumed. As our operations are composed of four reporting units (Americas, Europe/Africa/Middle East, Japan and Asia Pacific), we review the recoverability of goodwill by comparing each unit's fair value to the net book value of its assets. If the book value of the reporting unit's assets exceeds its fair value, the goodwill is written down to its implied fair value.

Additionally, we review the carrying amount of goodwill whenever events and circumstances indicate that the carrying amount of goodwill may not be recoverable. Impairment indicators include, among other conditions, cash flow deficits, historic or anticipated declines in revenue or operating profit and adverse legal or regulatory developments. If it is determined that such indicators are present and the review indicates that goodwill will not be fully recoverable, based upon discounted estimated cash flows, the carrying value is reduced to estimated fair market value. Estimated fair market value is determined primarily using the anticipated cash flows discounted at a rate commensurate with the risk involved.

In the second quarters of 2004, 2003 and 2002, we performed the annual impairment tests of goodwill, and no impairment was indicated based on these tests.

In accordance with Statement of Financial Accounting Standards No. 144 *Accounting for the Impairment or Disposal of Long-lived Assets*, we assess potential impairment to our long-lived assets when events or changes in circumstances indicate that the carrying amount of an asset may not be fully recoverable. If required, an impairment loss is recognized as the difference between the carrying value and the fair value of the assets.

**Table of Contents***Income Taxes*

We account for income taxes under the asset and liability method, whereby deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. We evaluate the need to establish a valuation allowance for deferred tax assets based upon the amount of existing temporary differences, the period in which they are expected to be recovered and expected levels of taxable income. A valuation allowance to reduce deferred tax assets is established when it is more likely than not that some or all of the deferred tax assets will not be realized.

*Stock-Based Compensation*

We measure stock-based compensation for option grants to employees and members of the board of directors using the intrinsic value method. The fair value of each option grant for determining the pro forma impact of stock-based compensation expense is estimated on the date of grant using the Black-Scholes option-pricing model with weighted average assumptions. These assumptions consist of expected dividend yield, expected volatility, expected life, and risk-free interest rate. If the assumptions used to calculate the value of each option grant do not properly reflect future activity, the weighted average fair value of our grants could be impacted.

*Acquired In-Process Research and Development*

Costs to acquire in-process research and development (IPR&D) projects and technologies which have no alternative future use and which have not reached technological feasibility at the date of acquisition are expensed as incurred. The fair value of IPR&D projects and technologies is estimated based upon management's assumptions such as projected regulatory approval dates, estimated future revenues and cost of goods sold of the products under development and expected sales and marketing costs. The major risks and uncertainties associated with the timely and successful completion of these projects consist of the ability to confirm the safety and efficacy of the technology based on the data from clinical trials and obtaining necessary regulatory approvals. In addition, no assurance can be given that the underlying assumptions used to forecast the cash flows or the timely and successful completion of such projects will materialize, as estimated. For these reasons, among others, actual results may vary from the estimated results.

**Comparing Fiscal Years Ended December 31, 2004, 2003 and 2002**

*Net sales.* The following table sets forth, for the periods indicated, net sales by geographic region and major product line.

<b>Year Ended December 31,</b>		
<b>2004</b>	<b>2003</b>	<b>2002</b>
(in thousands)		

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<b>United States:</b>			
Ophthalmic surgical	\$ 134,247	\$ 108,921	\$ 104,036
Eye care	52,635	44,537	47,247
	<u>          </u>	<u>          </u>	<u>          </u>
<b>Total United States</b>	<b>\$ 186,882</b>	<b>\$ 153,458</b>	<b>\$ 151,283</b>
	<u>          </u>	<u>          </u>	<u>          </u>
<b>Americas, excluding United States:</b>			
Ophthalmic surgical	\$ 20,139	\$ 15,359	\$ 14,195
Eye care	10,562	9,570	9,695
	<u>          </u>	<u>          </u>	<u>          </u>
<b>Total Americas, excluding United States</b>	<b>\$ 30,701</b>	<b>\$ 24,929</b>	<b>\$ 23,890</b>
	<u>          </u>	<u>          </u>	<u>          </u>
<b>Europe/Africa/Middle East:</b>			
Ophthalmic surgical	\$ 159,917	\$ 112,105	\$ 86,722
Eye care	103,806	99,991	87,157
	<u>          </u>	<u>          </u>	<u>          </u>
<b>Total Europe/Africa/Middle East</b>	<b>\$ 263,723</b>	<b>\$ 212,096</b>	<b>\$ 173,879</b>
	<u>          </u>	<u>          </u>	<u>          </u>
<b>Japan:</b>			
Ophthalmic surgical	\$ 62,856	\$ 46,370	\$ 45,788
Eye care	128,679	117,743	99,347
	<u>          </u>	<u>          </u>	<u>          </u>
<b>Total Japan</b>	<b>\$ 191,535</b>	<b>\$ 164,113</b>	<b>\$ 145,135</b>
	<u>          </u>	<u>          </u>	<u>          </u>
<b>Asia Pacific:</b>			
Ophthalmic surgical	\$ 36,263	\$ 23,753	\$ 19,654
Eye care	32,995	23,104	24,246
	<u>          </u>	<u>          </u>	<u>          </u>
<b>Total Asia Pacific</b>	<b>\$ 69,258</b>	<b>\$ 46,857</b>	<b>\$ 43,900</b>
	<u>          </u>	<u>          </u>	<u>          </u>
<b>Total net sales:</b>			
Ophthalmic surgical	\$ 413,422	\$ 306,508	\$ 270,395
Eye care	328,677	294,945	267,692
	<u>          </u>	<u>          </u>	<u>          </u>
<b>Total net sales</b>	<b>\$ 742,099</b>	<b>\$ 601,453</b>	<b>\$ 538,087</b>
	<u>          </u>	<u>          </u>	<u>          </u>
<b>U.S.</b>	<b>25.2%</b>	<b>25.5%</b>	<b>28.1%</b>
<b>International (excluding U.S.)</b>	<b>74.8%</b>	<b>74.5%</b>	<b>71.9%</b>

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We organize our operations into four regions: the Americas, which is comprised of North and South America, Europe/Africa/Middle East, Japan and Asia Pacific.

Net sales for 2004 increased by \$140.6 million, or 23.4%, to \$742.1 million in 2004 from \$601.5 million in 2003. The increase in 2004 was the result of sales of products acquired in the Acquisition, sales gains of existing products in both product lines and favorable foreign currency changes. Net sales of acquired products approximated \$75.8 million. Foreign currency fluctuations, particularly related to the Japanese yen and the euro, increased sales by \$37.5 million, or 6.2%, as compared to average rates in effect in 2003. Our sales and earnings may be negatively impacted during times of a strengthening U.S. dollar.

The U.S. information is presented separately as it is our headquarters country, and U.S. sales represented 25.2%, 25.5%, and 28.1% of total net sales in 2004, 2003 and 2002, respectively. Additionally, sales in Japan represented 25.8%, 27.3%, and 27.0% of total net sales in 2004, 2003 and 2002, respectively. No other country, or any single customer, generated over 10% of total net sales in any of these years.

Net sales in the Americas, including the United States, increased \$39.2 million in 2004 from 2003 and such increase was comprised of a \$30.1 million increase in sales of ophthalmic surgical products and a \$9.1 million increase in sales of eye care products. Net sales in the Americas include the favorable impact of foreign currency fluctuations of \$1.6 million. The increase in sales of ophthalmic surgical products includes \$21.0 million in sales of acquired products, including the *Healon* family of viscoelastics and *Tecnis* intraocular lenses, and increased sales of the *Sensar* intraocular lens and phacoemulsification products. The increase in sales of eye care products was primarily due to an increase in sales of *Complete* branded products.

Net sales in Europe/Africa/Middle East increased \$51.6 million in 2004 from 2003 and such increase was comprised of a \$47.8 million increase in sales of ophthalmic surgical products and a \$3.8 million increase in sales of eye care products. Net sales in Europe/Africa/Middle East include the favorable impact of foreign currency fluctuations of \$22.0 million primarily due to the strengthening of the euro versus the U.S. dollar. The increase in sales of ophthalmic surgical products includes \$31.1 million in sales of acquired products, including the *Healon* family of viscoelastics and *Tecnis* intraocular lenses, and increased sales of the *Sensar* intraocular lens and phacoemulsification products.

Net sales in Japan increased \$27.4 million in 2004 from 2003 and such increase was comprised of a \$16.5 million increase in sales of ophthalmic surgical products and a \$10.9 million increase in sales of eye care products. Net sales in Japan include the favorable impact of foreign currency fluctuations of \$11.8 million resulting from the strengthening of the Japanese yen versus the U.S. dollar. The increase in sales of ophthalmic surgical products includes \$18.2 million in sales of acquired products, including the *Healon* family of viscoelastics, and increased sales of the *Sensar* intraocular lens. The increase in sales of eye care products was primarily due to an increase in sales of *Complete* branded products and hydrogen peroxide-based products.

Net sales in Asia Pacific increased \$22.4 million in 2004 from 2003 and such increase was comprised of a \$12.5 million increase in sales of ophthalmic surgical products and a \$9.9 million increase in sales of eye care products. Net sales in Asia Pacific include the favorable impact of foreign currency fluctuations of \$2.1 million. The increase in sales of ophthalmic surgical products includes \$5.5 million in sales of acquired products, including the *Healon* family of viscoelastics and *CeeOn* intraocular lenses, and increased sales of the *Sensar* intraocular lens and phacoemulsification products. The increase in sales of eye care products was primarily due to an increase in sales of *Complete* branded products and hydrogen peroxide-based products.



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Global sales of our ophthalmic surgical products increased by \$106.9 million, or 34.9%, from 2003 to 2004. Sales of our ophthalmic surgical products increased primarily due to sales of acquired products of \$75.8 million, including the *Healon* family of viscoelastics and the *Tecnis* and *CeeOn* intraocular lenses, and increased sales of *Sensar* intraocular lenses and phacoemulsification products and favorable currency changes. Foreign currency fluctuations in 2004 increased international ophthalmic surgical sales by \$19.2 million, or 6.3%, as compared to average rates in effect in 2003. We believe that global sales of ophthalmic surgical products will continue to grow due to sales of acquired products, including the *Healon* family of viscoelastics, the *CeeOn* and *Tecnis* intraocular lenses and the *Baerveldt* glaucoma shunt, and increased sales of our *Sovereign Compact* phacoemulsification system with *WhiteStar* technology and the *Sensar* and the *ClariFlex* intraocular lenses, both with the *OptiEdge* design.

Global sales of our eye care products increased by \$33.7 million, or 11.4%, from 2003 to 2004. Sales of our eye care products increased primarily due to an increase in sales of *Complete* branded products and hydrogen peroxide-based products and favorable currency changes. Foreign currency fluctuations in 2004 increased international eye care sales by \$18.3 million, or 6.2%, as compared to average rates in effect in 2003. In the future, we expect global sales of our eye care products will continue to grow due to increased sales of our *Complete* branded products and continued sales growth in Europe and Asia Pacific.

Net sales for 2003 increased by \$63.4 million, or 11.8%, to \$601.5 million in 2003 from \$538.1 million in 2002. The increase in 2003 compared to 2002 was the result of increased sales in both product lines and favorable currency changes. Foreign currency fluctuations in 2003 increased sales by \$48.1 million, or 8.9%, as compared to average rates in effect in 2002.

Net sales in the Americas, including the United States, increased \$3.2 million in 2003 from 2002 and such increase was comprised of a \$6.0 million increase in sales of ophthalmic surgical products partially offset by a \$2.8 million decrease in sales of eye care products. Net sales in the Americas include the favorable impact of foreign currency fluctuations of \$1.9 million. The increase in sales of ophthalmic surgical products was primarily due to sales of the *Sovereign Compact* phacoemulsification system with *WhiteStar* technology and increased sales of the *Sensar* intraocular lens. The decrease in sales of eye care products was primarily due to a decrease in sales of hydrogen peroxide-based products and private-label products partially offset by an increase in sales of *Complete* branded products.

Net sales in Europe/Africa/Middle East increased \$38.2 million in 2003 from 2002 and such increase was comprised of a \$25.4 million increase in sales of ophthalmic surgical products and a \$12.8 million increase in sales of eye care products. Net sales in Europe/Africa/Middle East include the favorable impact of foreign currency fluctuations of \$31.7 million primarily due to the strengthening of the euro versus the U.S. dollar. The increase in sales of ophthalmic surgical products was primarily due to increased sales of the *Sensar* intraocular lens and phacoemulsification products. The increase in sales of eye care products was primarily due to an increase in sales of *Complete* branded products.

Net sales in Japan increased \$19.0 million in 2003 from 2002 and such increase was comprised of a \$0.6 million increase in sales of ophthalmic surgical products and an \$18.4 million increase in sales of eye care products. Net sales in Japan include the favorable impact of foreign currency fluctuations of \$12.1 million resulting from the strengthening of the Japanese yen versus the U.S. dollar. The increase in sales of eye care products was primarily due to an increase in sales of *Complete* branded products and hydrogen peroxide-based products.

Net sales in Asia Pacific increased \$3.0 million in 2003 from 2002 and such increase was comprised of a \$4.1 million increase in sales of ophthalmic surgical products partially offset by a \$1.1 million decrease in sales of eye care products. Net sales in Asia Pacific include the favorable impact of foreign currency fluctuations of \$2.4 million. The increase in sales of ophthalmic surgical products was primarily due to increased sales of intraocular lenses and phacoemulsification products. The decrease in sales of eye care products was primarily due to a decrease in sales of hydrogen peroxide-based products.

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Global sales of our ophthalmic surgical products increased by \$36.1 million, or 13.4%, from 2002 to 2003. Sales of our ophthalmic surgical products increased primarily due to sales of the *Sovereign Compact* phacoemulsification system with *WhiteStar* technology and the *Sensar* acrylic intraocular lens and favorable foreign currency changes. Foreign currency fluctuations in 2003 increased international ophthalmic surgical sales by \$23.3 million, or 8.6%, as compared to average rates in effect in 2002.

Global sales of our eye care products increased by \$27.3 million, or 10.2%, from 2002 to 2003. Sales of our eye care products increased primarily due to an increase in sales of our *Complete* branded products and favorable currency changes. Foreign currency fluctuations in 2003 increased international eye care sales by \$24.8 million, or 9.3%, as compared to average rates in effect in 2002.

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For additional information relating to our geographic operating segments, including operating income or loss and long-lived assets, see Note 13 of Notes to Consolidated Financial Statements.

*Income and expenses.* The following table sets forth certain statement of operations items as a percentage of net sales:

	Year Ended December 31,		
	2004	2003	2002
Net sales	100.0%	100.0%	100.0%
Cost of sales	41.3	37.9	38.0
Gross margin	58.7	62.1	62.0
Other operating costs and expenses:			
Selling, general and administrative	44.4	46.0	43.8
Research and development	6.1	6.2	5.6
In-process research and development	3.8		
Operating income	4.4	9.9	12.6
Interest expense	(3.6)	(4.0)	(2.6)
Loss on investments, net			(0.7)
Unrealized (loss) gain on derivative instruments			(0.6)
Other non-operating expense, net	(17.1)	(3.0)	(0.4)
Earnings (loss) before income taxes	(16.3)%	2.9%	8.3%
Net earnings (loss)	(17.4)%	1.7%	4.8%

*Gross margin.* Our gross margin percentage decreased as a percent of net sales by 3.4 percentage points to 58.7% in 2004 from 62.1% in 2003. Gross profit for 2004 included a charge of \$28.1 million (\$19.1 million, net of tax), or 3.8 percentage point impact on gross margin percentage, for manufacturing profit capitalized in inventory and expensed related to the Acquisition. In addition, pre-production costs incurred at our manufacturing facility in Madrid, Spain, costs incurred for expansion of our manufacturing facility in Hangzhou, China, and higher costs of product supplied by Allergan contributed to the gross margin percentage decrease, which was partially offset by sales growth in the higher margin *Complete* branded line of eye care products and sales of the *Healon* family of viscoelastics. In 2005, we expect our gross margin percentage to be favorably impacted as we fully transition manufacturing of our eye care products from Allergan and continue to shift our sales mix to higher margin products, including the *Healon* family of viscoelastics and the *Sensar* intraocular lens. Our gross margin percentage remained relatively constant in 2003 as compared to 2002. Our gross margin in 2002 was negatively impacted by the June 2002 write-off of \$2.6 million of inventory deemed unusable due to our spin-off from Allergan.

*Selling, general and administrative.* Selling, general and administrative expenses decreased as a percent of net sales by 1.6 percentage points to 44.4% in 2004 from 46.0% in 2003. Selling, general and administrative expenses for 2004 include an aggregate \$2.3 million (\$1.6 million, net of tax) charge to terminate a distributor contract following the decision to move to a direct sales model in Belgium as a result of the Acquisition and severance paid to AMO employees considered redundant upon completion of the Acquisition and amortization of \$5.6 million related to the acquired intangible assets. Amortization of intangible assets was \$0.1 million and \$1.0 million in 2003 and 2002, respectively. In 2004, selling, general and administrative expenses also include an additional \$9.3 million in acquisition integration-related charges. Selling, general and administrative expenses increased as a percent of net sales by 2.2 percentage points to 46.0% in 2003 from 43.8% in 2002. This increase was primarily the result of increased sales and marketing efforts in the global eye care business and incremental costs associated with running an

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independent public company. Additionally, we increased our allowance for doubtful accounts by \$3.1 million and \$3.5 million in 2003 and 2002, respectively, primarily as a result of deterioration in the aging of certain customer accounts in Europe.

*Research and development.* Research and development expenditures as a percent of net sales remained relatively constant in 2004 as compared to 2003 and increased by 0.6 percentage points to 6.2% in 2003 from 5.6% in 2002. As a result of our continued investment in research and development and other business development activities, we launched our new vitreal retinal system, *AMO Gemini*, in Europe, the *StabilEyes* capsular tension ring in North America, the *ReZoom* intraocular lens in Europe, an advanced formulation of our *blink* contact lens rewetter in the U.S. and Europe, the *Complete AquaVision* contact lens in Europe and the *Verisyse* phakic intraocular lens for correction of myopia in the U.S. In 2005, we expect to bring to market the *ReZoom* intraocular lens and *Vitrax II* in the U.S. and several new eye care products in Japan.

*In-process research and development.* In 2004, we incurred an in-process research and development (IPR&D) charge of \$28.1 million (\$28.1 million, net of tax) related to the Acquisition. This charge represented the estimated fair value of projects that, as of the Acquisition date, had not reached technological feasibility and had no alternative future use. The estimated fair value assigned to IPR&D was comprised of the following projects: *Tecnis* Monofocal - \$1.6 million and

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*Tecnis Multifocal* - \$26.5 million. The estimated fair value of these IPR&D projects was estimated by performing a discounted cash flow analysis using the income approach. For each project, the estimated after-tax cash flows were probability weighted to take into account the stage of completion and the risks surrounding the successful development and commercialization. These cash flows were then discounted to a present value using a discount rate of 14.5%. Regulatory approval for the *Tecnis Monofocal* in Japan is expected in 2005. We also estimate that the *Tecnis Multifocal* will receive its PMA in the U.S. in 2008, with approval in Japan in 2008. Additional research and development expenses in the range of \$0.5 million to \$1.0 million and \$2.5 million to \$3.0 million for the *Tecnis Monofocal* and the *Tecnis Multifocal*, respectively, represent our best estimate as to the additional research and development expenses to bring these products to market. These projects are currently on track for these approval dates. However, the major risks and uncertainties associated with the timely and successful completion of these projects consist of the ability to confirm the safety and efficacy of the technology based on the data from clinical trials and obtaining the necessary approvals. We can provide no assurance that the approvals will be received on this schedule or at all.

*Operating income.* Operating income was \$33.0 million, \$59.5 million and \$67.9 million in 2004, 2003 and 2002, respectively. Our 2004 operating income included an aggregate \$58.5 million (\$48.8 million, net of tax) in charges related to the manufacturing profit capitalized in inventory and expensed, the distributor contract termination and severance and in-process research and development as discussed above.

*Non-operating expense.* Interest expense was \$26.9 million, \$24.2 million and \$13.8 million in 2004, 2003 and 2002, respectively. In 2004, interest expense included a net charge of \$6.5 million (\$3.9 million, net of tax) comprised of a charge of \$9.7 million for the pro-rata write-off of debt issuance costs and write-off of original issue discount and one-time commitment fees net of a net realized gain on interest rate swaps of \$3.2 million, all associated with the prepayment of the Japan term loan in June 2004, consummation of the June 2004 tender offer for \$70.0 million aggregate principal amount of 9 1/4% senior subordinated notes (Senior Subordinated Notes), the exchange of \$131.4 million aggregate principal amount of 3 1/2% convertible senior subordinated notes (Existing Notes) and partial prepayment of the \$250.0 million June 2004 term loan. Interest expense in 2003 included a net charge of \$5.8 million (\$3.5 million, net of tax) comprised of a charge of \$7.8 million for the pro-rata write-off of debt issuance costs and write-off of original issue discount net of a net realized gain on interest rate swaps of \$2.0 million associated with the prepayment of a term loan in June 2003, the consummation of the Modified Dutch Auction tender offer for \$115.0 million aggregate principal amount of Senior Subordinate Notes in July 2003 and the repurchase of an additional \$15.0 million aggregate principal amount of Senior Subordinate Notes in September 2003. We expect interest expense to be higher in 2005 as compared to 2004 due to the additional debt incurred to finance the Acquisition as well as the additional \$200.0 million of debt expected to be incurred to fund certain transaction fees and the cash consideration portion of the proposed acquisition of VISX, Incorporated.

Loss on investments is comprised of a \$3.9 million charge for the other than temporary impairment of equity investments in 2002.

We recorded an unrealized loss on derivative instruments of \$0.4 million, \$0.2 million and \$3.2 million in 2004, 2003 and 2002 respectively. We record as unrealized loss (gain) on derivative instruments the mark to market adjustments on the outstanding foreign currency options which we entered into or were allocated as part of Allergan's overall risk management strategy to reduce the volatility of expected earnings in currencies other than the U.S. dollar.

The loss due to exchange of 3 1/2% Convertible Senior Subordinated Notes due 2023 of \$116.3 million is comprised of a non-cash charge of \$111.7 million (\$111.7 million, net of tax) and a cash charge of \$4.6 million (\$4.6 million, net of tax). In the quarter ended June 25, 2004, we exchanged approximately 5.8 million shares of common stock and \$4.6 million of cash for approximately \$108.6 million in aggregate principal amount of these notes. Because these notes were not convertible into equity at such time, a non-cash charge of \$107.2 million and a cash charge of \$4.6 million was recorded. The \$107.2 million non-cash charge was comprised of a charge of \$89.1 million representing the difference between the fair market value of 5.3 million shares of common stock issued in exchange for the notes and the principal amount of notes exchanged and a charge of \$18.1 million representing the fair market value of 0.5 million shares of common stock issued as a premium. The \$4.6 million cash charge represented cash issued as a premium. In the remainder of 2004, we exchanged approximately 1.2 million shares of common stock for approximately \$22.8 million in aggregate principal amount of these notes. As a result, a non-cash charge of \$4.5 million representing the fair value of shares issued as a premium was recorded. In the future, additional losses may be incurred, if we exchange additional shares of common stock for all or a portion of the remaining notes.

Other non-operating expense of \$10.6 million for 2004 included \$10.8 million paid for the repurchase of the Senior Subordinated Notes and early debt extinguishment costs and fees of \$0.1 million aggregating \$10.9 million (\$6.5 million, net of taxes) partially offset by foreign exchange gains and interest income. Other non-operating expense of \$17.8 million for 2003 included an aggregate premium of \$19.4 million paid for the partial repurchase of the Senior Subordinated Notes net of

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a foreign currency gain of \$2.7 million resulting from the settlement of certain intercompany notes and related transfer of cash utilized for the prepayment of a term loan and partial repurchase of Senior Subordinated Notes, which aggregated \$16.8 million (\$10.1 million, net of taxes). Other non-operating expense of \$2.4 million in 2002 included early debt extinguishment costs of \$3.5 million (\$2.0 million, net of tax) associated with the prepayment of debt in Japan in June 2002 partially offset by foreign exchange gains.

*Income taxes.* In 2004, we recorded a provision for income taxes of \$8.2 million even though we had a pre-tax loss of \$121.2 million. We recorded such provision as no tax benefit has been recognized for the in-process research and development charge of \$28.1 million nor for the aggregate charge of \$116.3 million related to the exchange of the Existing Notes. Income taxes are provided on taxable income at the statutory rates applicable to such income and we have provided for U.S. federal income taxes and foreign withholding taxes on the undistributed earnings of non-U.S. subsidiaries. We believe our future effective income tax rate may vary depending on our mix of domestic and international taxable income or loss and the various tax and treasury methodologies that we implement, including our policy regarding repatriation of future accumulated foreign earnings. We expect our effective tax rate on continuing operations to continue to be in the low to mid 30 percent range in 2005.

The American Jobs Creation Act of 2004 was signed into law in October 2004, which allows companies to elect to repatriate cash into the United States in 2005 at a special, temporary effective tax rate of 5.25 percent. Our evaluation of the amount of foreign earnings that we may elect to treat under this special provision, and the financial statement impact, is in process. As such, we are not in a position to decide on whether, and to what extent, our foreign earnings will be affirmatively designated for this treatment. The related potential range of the income tax effect of the repatriation cannot be reasonably estimated at this time. We expect to be in a position to finalize our assessment by the end of the third quarter in 2005.

Our effective tax rate in 2003 was 40%, as compared to 41.9% in 2002. The decrease in 2003 was primarily attributable to the utilization of foreign tax credits.

In accordance with Emerging Issues Task Force Issue No. 94-10, *Accounting by a Company for the Income Tax Effects of Transactions among or with Its Shareholders under FASB Statement No. 109*, we established deferred tax assets of approximately \$17.5 million as of December 31, 2002 through a credit to equity for all differences resulting from the spin-off in the financial reporting and tax bases of certain assets and liabilities. These differences occurred in jurisdictions where the transfer of assets and liabilities to us in the spin-off was deemed to be a taxable transaction. In such situations, the tax bases were adjusted to reflect the fair market value of the assets and liabilities on the spin-off date whereas the financial reporting bases were unchanged.

*Net earnings (loss).* Net earnings (loss) was \$(129.4) million, \$10.4 million and \$25.9 million in 2004, 2003 and 2002, respectively. The net loss in 2004 included an aggregate after-tax charge of \$175.5 million related to the following: the manufacturing profit capitalized in inventory and expensed related to the Acquisition; the charge to terminate a distributor contract following the decision to move to a direct sales model in Belgium as a result of the Acquisition and severance paid to AMO employees considered redundant upon completion of the Acquisition; the in-process research and development charge related to the Acquisition; the pro-rata write-off of debt issuance costs and write-off of original issue discount net of a net realized gain on interest rate swaps; and the charges related to the repurchase of the Senior Subordinated Notes and the exchange of the Existing Notes.

Net earnings in 2003 included an aggregate after-tax charge of \$13.5 million related to the pro-rata write-off of debt issuance costs and write-off of original issue discount net of a net realized gain on interest rate swaps and a net charge related to the prepayment of a term loan and partial repurchase of Senior Subordinated Notes.

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Net earnings in 2002 included the after-tax charge of \$2.0 million related to the prepayment of debt in Japan.

*Seasonality.* Historically, we have realized a seasonal trend in our sales, with the smallest portion of our ophthalmic surgical sales being realized in the first quarter and with sales gradually increasing from the second to fourth quarter. We believe sales of our ophthalmic surgical products are comparatively higher in the fourth quarter because hospitals, ambulatory surgical centers and other customers increase spending as they reach their year-end and are able to spend the remainder of their annual budgeted amounts. As a result of acquisitions and expanded product offerings, we expect to realize less seasonality in future periods as we seek to diversify our sales geographically and with more products that are less seasonal.



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### **Liquidity and Capital Resources**

Management assesses our liquidity by our ability to generate cash to fund operations. Significant factors in the management of liquidity are: funds generated by operations; levels of accounts receivable, inventories, accounts payable and capital expenditures; adequate lines of credit; and financial flexibility to attract long-term capital on satisfactory terms. As of December 31, 2004, we had cash and equivalents of \$49.5 million.

Historically, we have generated cash from operations in excess of working capital requirements, and we expect to do so in the future. Net cash provided by operating activities in 2004 was \$39.7 million compared to \$48.0 million in 2003 and \$126.9 million in 2002. Operating cash flow decreased in 2004 compared to 2003 primarily as a result of early debt extinguishment costs paid in cash and an increase in accounts receivable partially offset by an increase in accounts payable. The increase in accounts receivable and accounts payable is primarily due to increased activities resulting from the Acquisition and the ongoing transition of eye care manufacturing from Allergan. Additionally, in February 2004, we received approximately \$4.7 million from Allergan. This payment ended a dispute between us and Allergan regarding the ownership of a certain value added tax receivable due from France. As part of the settlement with Allergan, we were responsible for paying penalties and expenses associated with the receivable, which aggregated less than \$0.5 million. Operating cash flow decreased in 2003 compared to 2002 primarily as a result of lower net earnings due to the additional costs of our operations as an independent company, early debt extinguishment costs and a decrease in accounts payable.

The 2004 capital expenditures are primarily comprised of expansion of our manufacturing facilities in preparation for the transition away from the Allergan manufacturing agreement, expenditures at the acquired manufacturing facilities and construction of research and development facilities at our leased headquarters. Net cash used in investing activities was \$482.2 million, \$41.1 million, and \$22.1 million in 2004, 2003 and 2002, respectively. The 2004 amount includes the \$456.7 million Acquisition purchase price, which was financed with a portion of the proceeds from the issuance of \$350.0 million of Notes and a \$250.0 million term loan noted below. In November 2003, we completed the purchase of an existing manufacturing facility in Madrid, Spain. We financed the approximately \$21.4 million purchase of this facility with available cash and borrowings under our senior credit facility. Expenditures for property, plant and equipment totaled \$17.5 million, \$12.6 million, and \$16.7 million in 2004, 2003, and 2002, respectively. We expect to incur significant capital expenditures with respect to the Uppsala, Sweden manufacturing facility during the next two years in order to separate the facility from existing Pfizer operations. The decrease in expenditures in 2003 as compared to 2002 is primarily due to the large amount of improvements to our leased headquarters during 2002. The 2002 expenditures were primarily comprised of improvements to our leased headquarters and also include expansion of manufacturing facilities and a variety of other projects designed to improve productivity. Expenditures for demonstration (demo) and bundled equipment, primarily phacoemulsification and microkeratome surgical equipment, were \$6.8 million, \$7.0 million, and \$5.0 million in 2004, 2003, and 2002, respectively. We maintain demo and bundled equipment to facilitate future sales of similar equipment and related products to our customers. Expenditures for capitalized internal-use software were \$2.4 million, \$0.7 million, and \$0.9 million in 2004, 2003, and 2002, respectively. We capitalize internal-use software costs after technical feasibility has been established. In 2005, we expect to invest approximately \$65.0 million to \$70.0 million in property, plant and equipment, demo and bundled equipment, and capitalized software as part of the overall expansion of our business.

Net cash provided by financing activities was \$442.2 million in 2004, which was primarily comprised of \$350.0 million of proceeds from the issuance of 2 1/2% convertible senior subordinated notes due 2024 (Notes) and a \$250.0 million term loan, partially offset by repayment of debt of \$149.2 million and financing related costs of \$16.6 million.

Net cash used in financing activities was \$43.5 million in 2003, which was primarily comprised of \$162.4 million of long-term debt borrowings and \$6.0 million from the sale of stock to employees reduced by long-term debt repayments of \$205.0 million and financing related costs of \$7.3 million.

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Net cash used in financing activities was \$32.2 million in 2002, which was comprised of \$305.6 million of long-term debt borrowings and \$5.6 million of net proceeds from the settlement of an interest rate swap offset by long-term debt repayments of \$136.4 million, financing related costs of \$10.3 million and \$196.7 million of net distributions to Allergan. A majority of cash generated from operations prior to June 28, 2002 was transferred to Allergan. Net transfers to Allergan ceased as of June 28, 2002 as a result of the spin-off.

In 2004, the following transactions occurred: our Japan subsidiary repaid its ¥2.5 billion, approximately \$22.4 million, term loan facility; we consummated the offering of \$350.0 million of the Notes; we consummated a tender offer to repurchase the remaining \$70.0 million aggregate principal amount of Senior Subordinated Notes; and we exchanged \$131.4 million aggregate principal amount of Existing Notes for common stock and cash. In addition, in June 2004 we amended and restated our senior credit facility to provide a \$250.0 million term loan and a \$100.0 million revolving credit facility. As of December 31, 2004, we did not have any borrowings outstanding under the revolving credit facility and the term loan balance had been reduced to \$194.0 million.

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In January 2005, we entered into an amendment to our senior credit facility to provide for an increase by \$100.0 million in the revolving loan commitments and an additional \$100.0 million in term loan commitments. We expect to utilize this additional \$200.0 million to fund certain transaction fees and the cash consideration portion of the proposed acquisition of VISX, Incorporated, which we announced on November 9, 2004.

The senior credit facility provides that we will maintain certain financial and operating covenants which include, among other provisions, maintaining specific leverage and interest coverage ratios. Certain covenants under the senior credit facility and the indenture relating to the senior subordinated notes also limit the incurrence of additional indebtedness. The senior credit facility prohibits cash dividend payments. We were in compliance with these covenants at December 31, 2004.

Our cash position includes amounts denominated in foreign currencies, and the repatriation of those cash balances from some of our non-U.S. subsidiaries may result in additional tax costs. However, these cash balances are generally available without legal restriction to fund ordinary business operations.

We believe that the net cash provided by our operating activities, supplemented as necessary with borrowings available under our revolving credit facility and existing cash and equivalents, will provide sufficient resources to provide the required funding for the proposed acquisition of VISX, Incorporated, to fund the expected 2005 capital expenditures, and to meet our working capital requirements, debt service and other cash needs over the next year.

We are partially dependent upon the reimbursement policies of government and private health insurance companies. Government and private sector initiatives to limit the growth of health care costs, including price regulation and competitive pricing, are continuing in many countries where we do business. As a result of these changes, the marketplace has placed increased emphasis on the delivery of more cost-effective medical therapies. While we have been unaware of significant price resistance resulting from the trend toward cost containment, changes in reimbursement policies and other reimbursement methodologies and payment levels could have an adverse effect on our pricing flexibility.

Additionally, the current trend among U.S. hospitals and other customers of medical device manufacturers is to consolidate into larger purchasing groups to enhance purchasing power. The enhanced purchasing power of these larger customers may also increase the pressure on product pricing, although we are unable to estimate the potential impact at this time.

*Inflation.* Although at reduced levels in recent years, inflation may cause upward pressure on the cost of goods and services used by us. The competitive and regulatory environments in many markets substantially limit our ability to fully recover these higher costs through increased selling prices. We continually seek to mitigate the adverse effects of inflation through cost containment and improved productivity and manufacturing processes.

*Foreign currency fluctuations.* Approximately 75%, 74%, and 72% of our revenues in the years ended December 31, 2004, 2003 and 2002, respectively, were derived from operations outside the United States, and a significant portion of our cost structure is denominated in currencies other than the U.S. dollar, primarily the Japanese yen and the euro. Therefore, we are subject to fluctuations in sales and earnings reported in U.S. dollars as a result of changing currency exchange rates.

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The impact of foreign currency fluctuations on sales was a \$37.5 million, \$48.1 million and \$5.2 million increase in 2004, 2003 and 2002, respectively. The sales increases were due primarily to a strengthening of the Japanese yen and euro versus the U.S. dollar.

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*Contractual obligations.* The following represents a list of our material contractual obligations and commitments as of December 31, 2004:

	Payments Due by Year						Total
	2005	2006	2007	2008	2009	Thereafter	
	(in millions)						
Long-term debt, principal amount	\$ 1.9	\$ 2.0	\$ 1.9	\$ 94.6	\$ 93.6	\$ 358.6	\$ 552.6
Cash commitments for interest expense	18.4	18.1	17.8	17.8	13.3	131.4	216.8
Operating lease obligations	15.6	8.0	5.3	4.4	3.9	22.1	59.3
IT services	5.4	5.2	4.7				15.3
Other purchase obligations, primarily purchases of inventory and capital equipment	70.9	1.5	0.5	0.1			73.0

**New Accounting Standards**

In September 2004, the Emerging Issues Task Force finalized its consensus on EITF Issue No. 04-8, *The Effect of Contingently Convertible Debt on Diluted Earnings Per Share* (EITF 04-8). EITF 04-8 addresses when the dilutive effect of contingently convertible debt with a market price trigger should be included in diluted earnings per share (EPS). Under EITF 04-8, the market price contingency should be ignored and these securities should be treated as non-contingent, convertible securities and always included in the diluted EPS computation. EITF 04-8 requires these securities be included in diluted EPS using either the if-converted method or the net share settlement method, depending on the conversion terms of the security. EITF 04-8 is effective for all periods ending after December 15, 2004 and is to be applied by retrospectively restating previously reported EPS. We irrevocably elected to cash settle the principal amount of the Notes and thus, the dilutive effect of the Notes was calculated under the net share settlement method. Adoption of EITF 04-8 did not have an impact on EPS for the years ended December 31, 2004 and 2003, as the impact of the Existing Notes, which were issued in June 2003, is antidilutive.

In November 2004, Statement of Financial Accounting Standards No. 151, *Inventory Costs—an amendment of ARB No. 43, Chapter 4* (SFAS No. 151), was issued. This Statement amends the guidance in ARB No. 43, Chapter 4, *Inventory Pricing*, to clarify the accounting for abnormal amounts of idle facility expense, freight, handling costs, and wasted material (spoilage). SFAS No. 151 is effective for inventory costs incurred during fiscal years beginning after June 15, 2005. We do not expect adoption of this standard to have a material impact on our consolidated financial statements.

In December 2004, the Financial Accounting Standards Board issued a revision of Statement of Financial Accounting Standards No. 123, *Accounting for Stock-Based Compensation* (SFAS No. 123R). SFAS No. 123R supersedes APB Opinion No. 25, *Accounting for Stock Issued to Employees*, and its related implementation guidance and eliminates the alternative to use Opinion 25's intrinsic value method of accounting that was provided in Statement 123 as originally issued. Under Opinion 25, issuing stock options to employees generally resulted in recognition of no compensation cost. SFAS No. 123R requires entities to recognize the cost of employee services received in exchange for awards of equity instruments based on the grant-date fair value of those awards (with limited exceptions). SFAS No. 123R is effective for the first interim or annual reporting period that begins after June 15, 2005. We have not quantified the potential effect of adoption of SFAS No. 123R. However, we believe adoption of SFAS No. 123R will result in a decrease to our reporting earnings.

**Item 7A. Quantitative and Qualitative Disclosures About Market Risk**

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We routinely monitor our risks associated with fluctuations in currency exchange rates and interest rates. We address these risks through controlled risk management that may include the use of derivative financial instruments to economically hedge or reduce these exposures. We do not expect to enter into financial instruments for trading or speculative purposes. For fiscal 2002 through June 28, 2002, we were considered in Allergan's overall risk management strategy. As part of this strategy, Allergan managed its risks based on management's judgment of the appropriate trade-off between risk, opportunity and costs. With respect to our risks, Allergan primarily utilized foreign currency option and forward contracts to economically hedge or reduce these exposures.

Given the inherent limitations of forecasting and the anticipatory nature of the exposures intended to be hedged, there can be no assurance that such programs will offset more than a portion of the adverse financial impact resulting from unfavorable movements in either interest or foreign exchange rates. In addition, the timing of the accounting for recognition of gains and losses related to mark-to-market instruments for any given period may not coincide with the timing of gains and losses related to the underlying economic exposures and, therefore, may adversely affect our operating results and financial position.

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To ensure the adequacy and effectiveness of our interest rate and foreign exchange hedge positions, we continually monitor, from an accounting and economic perspective, our interest rate swap positions and foreign exchange forward and option positions, when applicable, both on a stand-alone basis and in conjunction with our underlying interest rate and foreign currency exposures.

*Interest rate risk.* At December 31, 2004, our debt is comprised solely of domestic borrowings and is comprised of \$358.6 million of fixed rate debt and \$194.0 million of variable rate debt.

In July 2004, we entered into an interest rate swap agreement, which effectively converts the interest rate on \$125.0 million of term loan borrowings from a floating rate to a fixed rate. This interest rate swap matures in July 2006 and qualifies as a cash flow hedge. Changes in fair value of the interest rate swap agreement are recorded in other comprehensive income to the extent such changes are effective and as long as the cash flow hedge requirements are met. At December 31, 2004, the fair value of \$0.3 million of the interest rate swap is recorded in Other assets in the accompanying consolidated balance sheet.

We had previously entered into various interest rate swap agreements, which effectively converted the interest rate on \$150.0 million of the Senior Subordinated Notes from a fixed to a floating rate and converted the interest rate on \$50.0 million of term loan borrowings from a floating to a fixed rate. The interest rate swaps had maturity dates beginning in 2005 and qualified as either fair value or cash flow hedges. Changes in fair value of the interest rate swap agreement qualifying as a cash flow hedge were recorded in other comprehensive income to the extent such changes were effective and as long as the cash flow hedge requirements were met. In May 2003 and October 2002, we realized the value of the interest rate swaps qualifying as fair value hedges. We received an aggregate of approximately \$14.8 million, of which approximately \$6.3 million represented the net settlement of the accrued but unpaid amount between us and the swap counterparties. The remaining amount of approximately \$8.5 million was recorded as an adjustment to the carrying amount of the Senior Subordinated Notes as a premium and was being amortized over the remaining life of the Senior Subordinated Notes. At December 31, 2003, after recognizing a pro-rata portion of the gain upon repurchase of a portion of the Senior Subordinated Notes, the unamortized gain on these interest rate swaps was \$3.5 million. As a result of the June 2004 repurchase of the remaining Senior Subordinated Notes, the remaining unamortized gain on the interest rate swaps was fully recognized.

In May 2003, we terminated the interest rate swap qualifying as a cash flow hedge. We paid approximately \$2.4 million and included the related loss of approximately \$2.3 million as a component of accumulated other comprehensive income. As a result of the prepayment of the term loan in June 2003, the loss on the interest rate swap was fully recognized as interest expense.

The tables below present information about our debt obligations and interest rate derivatives for the years ended December 31, 2004 and 2003:

**December 31, 2004**

Maturing in							Fair Market Value
2005	2006	2007	2008	2009	Thereafter	Total	

(in thousands, except interest rates)

**LIABILITIES****Debt Obligations:**

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Fixed Rate	\$	\$	\$	\$	\$	\$ 350,000	\$ 350,000	\$ 379,750
Weighted Average Interest Rate						2.50%	2.50%	
Fixed Rate	\$	\$	\$	\$	\$	\$ 8,600	\$ 8,600	\$ 18,311
Weighted Average Interest Rate						3.50%	3.50%	
Variable Rate	\$ 1,950	\$ 1,950	\$ 1,950	\$ 94,559	\$ 93,584	\$	\$ 193,993	\$ 193,993
Weighted Average Interest rate	4.50%	4.50%	4.50%	4.50%	4.50%		4.50%	
Total Debt Obligations	\$ 1,950	\$ 1,950	\$ 1,950	\$ 94,559	\$ 93,584	\$ 358,600	\$ 552,593	\$ 592,054
Weighted Average Interest rate	4.50%	4.50%	4.50%	4.50%	4.50%	2.52%	3.22%	

**INTEREST RATE**

**DERIVATIVES**

**Interest Rate Swaps:**

Variable to Fixed	\$	\$ 125,000	\$	\$	\$	\$	\$ 125,000	\$ 319
Average Pay Rate		3.05%					3.05%	
Average Receive Rate		2.57%					2.57%	



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December 31, 2003

	Maturing in						Fair Market Value	
	2004	2005	2006	2007	2008	Thereafter		Total
(in thousands, except interest rates)								
<b>LIABILITIES</b>								
<b>Debt Obligations:</b>								
Fixed Rate	\$	\$	\$	\$	\$	\$ 70,000	\$ 70,000	\$ 76,524
Weighted Average Interest Rate						9.25%	9.25%	
Fixed Rate	\$	\$	\$	\$	\$	\$ 140,000	\$ 140,000	\$ 170,320
Weighted Average Interest Rate						3.50%	3.50%	
Variable Rate	\$ 2,328	\$ 2,328	\$ 18,627	\$	\$	\$	\$ 23,283	\$ 23,283
Weighted Average Interest Rate	3.10%	3.10%	3.10%				3.10%	
Total Debt Obligations	\$ 2,328	\$ 2,328	\$ 18,627	\$	\$	\$ 210,000	\$ 233,283	\$ 270,127
Weighted Average Interest Rate	3.10%	3.10%	3.10%			5.42%	5.19%	

*Foreign currency risk.* Overall, we are a net recipient of currencies other than the U.S. dollar and, as such, we benefit from a weaker dollar and are adversely affected by a stronger U.S. dollar relative to major currencies worldwide. Accordingly, changes in exchange rates, and in particular a strengthening of the U.S. dollar, may negatively affect our consolidated net sales and gross profit as expressed in U.S. dollars.

We may enter into foreign exchange option and forward contracts to reduce earnings and cash flow volatility associated with foreign exchange rate changes to allow management to focus its attention on its core business operations. Accordingly, we enter into contracts which change in value as foreign exchange rates change to economically offset the effect of changes in value of foreign currency assets and liabilities, commitments and anticipated foreign currency denominated sales and operating expenses. We enter into foreign exchange option and forward contracts in amounts between minimum and maximum anticipated foreign exchange exposures, generally for periods not to exceed one year.

We use foreign currency option contracts, which provide for the sale of foreign currencies to offset foreign currency exposures expected to arise in the normal course of our business. While these instruments are subject to fluctuations in value, such fluctuations are anticipated to offset changes in the value of the underlying exposures. The principal currencies subject to this process are the Japanese yen and the euro.

The foreign currency options are entered into to reduce the volatility of earnings generated in currencies other than the U.S. dollar, primarily earnings denominated in Japanese yen and the euro. As a result, the changes in the fair value of outstanding foreign currency option contracts are recorded through earnings as Unrealized loss (gain) on derivative instruments while any realized gains or losses on expired contracts are recorded through earnings as Other, net in the accompanying consolidated statements of operations. The premium cost of purchased foreign exchange option contracts are recorded in Other current assets and amortized over the life of the options.

As part of Allergan's risk management strategy, foreign exchange forward contracts were entered into to protect the value of foreign currency denominated intercompany receivables and the changes in the fair value of the foreign currency forward contracts were economically designed to offset the changes in the revaluation of the foreign currency denominated intercompany receivables. As a result, our allocated portion of current changes in both the foreign currency forward contracts and revaluation of the foreign currency denominated intercompany receivables was recorded through Other, net in the accompanying consolidated statement of operations for fiscal 2002.

At December 31, 2004, the aggregate notional amounts and strike amounts of our outstanding yen and euro currency option contracts were \$67.3 million and 114.42 and \$56.9 million and 1.15, respectively. At December 31, 2003, the aggregate notional amounts and strike amounts of outstanding yen and euro currency option contracts were \$63.9 million and 120.62 and \$50.2 million and 1.09, respectively. The notional principal amount provides one measure of the transaction volume outstanding as of year end, and does not represent the amount of our exposure to market loss. The fair value of the foreign currency option contracts was \$0.1 million and \$0.4 million at December 31, 2004 and 2003, respectively. The estimate of fair value is based on applicable and commonly used prevailing financial market information as of December 31, 2004. The amounts ultimately realized upon settlement of these financial instruments, together with the gains and losses on the underlying exposures, will depend on actual market conditions during the remaining life of the instruments.

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Through June 28, 2002, our allocated portion of changes in the revaluation of foreign currency forward contracts and changes in the fair value of foreign currency option contracts was based on our percentage of net sales compared to total Allergan net sales. In the last half of 2002 and as part of the transitional services agreement with Allergan, we paid to Allergan the costs of certain yen denominated foreign currency option contracts previously entered into by Allergan. The impact of foreign exchange risk management transactions on income was a net realized loss of \$1.9 million, \$2.5 million and \$1.4 million in 2004, 2003 and 2002, respectively, and are recorded in Other, net in the accompanying consolidated statements of operations.

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**Item 8: Financial Statements and Supplementary Data**

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**Table of Contents****ADVANCED MEDICAL OPTICS, INC.****CONSOLIDATED BALANCE SHEETS**

	<b>As of December 31,</b>	
	<b>2004</b>	<b>2003</b>
	<b>(In thousands, except share data)</b>	
<b>ASSETS</b>		
Current assets		
Cash and equivalents	\$ 49,455	\$ 46,104
Trade receivables, net	189,465	130,423
Inventories	85,028	41,596
Deferred income taxes	40,250	24,124
Other current assets	12,627	10,245
	<u>376,825</u>	<u>252,492</u>
Total current assets	376,825	252,492
Property, plant and equipment, net	118,639	68,136
Deferred income taxes		7,556
Other assets	41,825	27,079
Intangible assets, net	147,895	369
Goodwill	391,350	105,713
	<u>1,076,534</u>	<u>461,345</u>
Total assets	\$ 1,076,534	\$ 461,345
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
Current liabilities		
Current portion of long-term debt	\$ 1,950	\$ 2,328
Accounts payable	77,824	35,605
Accrued compensation	31,451	24,507
Other accrued expenses	67,042	46,866
Income taxes	15,656	5,995
	<u>193,923</u>	<u>115,301</u>
Total current liabilities	193,923	115,301
Long-term debt, net of current portion	550,643	233,611
Deferred income taxes	29,570	
Other liabilities	26,128	19,241
Commitments and contingencies		
Stockholders' equity		
Preferred stock, \$.01 par value; authorized 5,000,000 shares, none issued		
Common stock, \$.01 par value; authorized 120,000,000 shares; issued 37,069,452 and 29,378,599 shares	371	294
Additional paid-in capital	310,437	54,064
Retained earnings (accumulated deficit)	(104,389)	24,981
Accumulated other comprehensive income	69,874	13,868
Less treasury stock, at cost (1,379 and 997 shares)	(23)	(15)
	<u>276,270</u>	<u>93,192</u>
Total stockholders' equity	276,270	93,192

Total liabilities and stockholders' equity	\$ 1,076,534	\$ 461,345
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See accompanying notes to consolidated financial statements.

**Table of Contents****ADVANCED MEDICAL OPTICS, INC.****CONSOLIDATED STATEMENTS OF OPERATIONS**

	Year Ended December 31,		
	2004	2003	2002
	(In thousands, except per share data)		
Net sales	\$ 742,099	\$ 601,453	\$ 538,087
Cost of sales	306,164	227,811	204,338
Gross profit	435,935	373,642	333,749
Selling, general and administrative	329,197	276,695	235,977
Research and development	45,616	37,413	29,917
In-process research and development	28,100		
Operating income	33,022	59,534	67,855
Non-operating expense			
Interest expense	26,933	24,224	13,764
Loss on investments, net			3,935
Unrealized loss on derivative instruments	403	246	3,199
Loss due to exchange of 3½% Convertible Senior Subordinated Notes due 2023 (note 5)	116,282		
Other, net	10,620	17,802	2,385
	154,238	42,272	23,283
Earnings (loss) before income taxes	(121,216)	17,262	44,572
Provision for income taxes	8,154	6,905	18,662
Net earnings (loss)	\$ (129,370)	\$ 10,357	\$ 25,910
Net earnings (loss) per share (note 1):			
Basic	\$ (3.89)	\$ 0.36	
Diluted	\$ (3.89)	\$ 0.35	
Weighted average number of shares outstanding:			
Basic	33,284	29,062	
Diluted	33,284	29,644	

See accompanying notes to consolidated financial statements.





**Table of Contents****ADVANCED MEDICAL OPTICS, INC.****CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY AND COMPREHENSIVE INCOME (LOSS)**

	Common Stock		Additional Paid-in Capital	Unearned Compensation	Retained Earnings (Accumulated Deficit)	Allergan Inc. Net Investment	Accumulated Other Comprehensive Income (Loss)	Treasury Stock		Total	Comprehensive Income (Loss)
	Shares	Par Value						Shares	Amount		
(in thousands)											
<b>Balance at December 31, 2001</b>		\$	\$	\$	\$	\$ 215,653	\$ (1,723)	\$		\$ 213,930	
Comprehensive income											
Net earnings prior to spin-off						11,286				11,286	\$ 11,286
Net earnings subsequent to spin-off					14,624					14,624	14,624
Other comprehensive income:											
Foreign currency translation adjustments							6,226			6,226	6,226
Unrealized loss on derivative instruments qualifying as cash flow hedges, net of \$814 of tax							(1,172)			(1,172)	(1,172)
<b>Total comprehensive income</b>											<b>\$ 30,964</b>
Issuance of common stock in connection with the spin-off (note 1)	28,724	287	80,094			(80,381)					
Dividends and distributions to Allergan, Inc., net of advances and \$17,513 of deferred tax assets resulting from the spin-off			(32,639)			(146,558)				(179,197)	
Purchase of treasury stock, at cost								(3)	(13)	(13)	
<b>Balance at December 31, 2002</b>	28,724	287	47,455		14,624		3,331	(3)	(13)	65,684	
Comprehensive income											
Net earnings					10,357					10,357	\$ 10,357
Other comprehensive income:											
Foreign currency translation adjustments, net of \$6,598 of tax							9,365			9,365	9,365
Unrealized gain on derivative instruments qualifying as cash flow hedges, net of \$1,745 of							2,507			2,507	2,507

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tax										
Reclassification adjustment for realized loss on derivatives included in net earnings, net of \$928 of tax						(1,335)		(1,335)		(1,335)
<b>Total comprehensive income</b>										<b>\$ 20,894</b>
Issuance of common stock under stock option plan	426	4	3,794							3,798
Issuance of common stock under stock purchase plans	217	2	2,040				13	118		2,160
Issuance of restricted stock	12	1	165	(166)						
Expense of compensation plan					102					102
Tax benefits from employee stock plans			674							674
Purchase of treasury stock, at cost							(11)	(120)		(120)
<b>Balance at December 31, 2003</b>	<b>29,379</b>	<b>294</b>	<b>54,128</b>	<b>(64)</b>	<b>24,981</b>	<b>13,868</b>	<b>(1)</b>	<b>(15)</b>	<b>93,192</b>	
Comprehensive loss										
Net loss					(129,370)				(129,370)	\$ (129,370)
Other comprehensive income:										
Foreign currency translation adjustments						55,799			55,799	55,799
Unrealized gain on derivative instrument qualifying as cash flow hedge, net of \$112 of tax						207			207	207
<b>Total comprehensive loss</b>										<b>\$ (73,364)</b>
Issuance of common stock in connection with convertible note exchanges	7,021	70	243,881							243,951
Issuance of common stock under stock option plan	490	5	4,934							4,939
Issuance of common stock under stock purchase plans	171	2	3,051							3,053
Issuance of restricted stock	8		265	(265)						
Expense of compensation plan					219					219
Tax benefits from employee stock plans			4,288							4,288
Purchase of treasury stock, at cost								(8)		(8)
<b>Balance at December 31, 2004</b>	<b>37,069</b>	<b>\$ 371</b>	<b>\$ 310,547</b>	<b>\$ (110)</b>	<b>\$ (104,389)</b>	<b>\$ 69,874</b>	<b>(1)</b>	<b>\$ (23)</b>	<b>\$ 276,270</b>	

See accompanying notes to consolidated financial statements.



**Table of Contents****ADVANCED MEDICAL OPTICS, INC.****CONSOLIDATED STATEMENTS OF CASH FLOWS**

	Year Ended December 31,		
	2004	2003	2002
	(in thousands)		
<b>Cash flows provided by operating activities</b>			
Net earnings (loss):	\$ (129,370)	\$ 10,357	\$ 25,910
Adjustments to reconcile net earnings (loss) to net cash provided by operating activities:			
Amortization and write-off of original issue discount and debt issuance costs	11,028	9,687	814
Amortization and write-off of net realized gain on interest rate swaps	(3,466)	(2,631)	
Depreciation and amortization	23,616	15,547	15,746
Deferred income taxes	(16,737)	(9,356)	4,150
Tax benefit from issuance of stock under stock plans	4,288	674	
In-process research and development	28,100		
Loss on exchange of convertible Senior Subordinated Notes	111,702		
Loss on investments and assets	1,047	756	5,788
Unrealized loss on derivatives	403	246	3,199
Expense of compensation plan	219	102	
Changes in assets and liabilities, net of effect of acquisition:			
Trade receivables	(48,459)	6,202	2,809
Inventories	13,198	7,214	19,041
Other current assets	(1,514)	5,396	(2,887)
Accounts payable	39,759	(8,882)	11,994
Accrued expenses and other liabilities	7,294	14,574	26,758
Income taxes	5,775	(2,174)	8,944
Other non-current assets	(7,215)	264	4,642
<b>Net cash provided by operating activities</b>	<b>39,668</b>	<b>47,976</b>	<b>126,908</b>
<b>Cash flows from investing activities</b>			
Acquisition of business, net of cash acquired	(456,709)		
Additions to property, plant and equipment	(17,492)	(12,605)	(16,737)
Purchase of net assets of manufacturing facility		(21,359)	
Proceeds from sale of property, plant and equipment	1,172	556	591
Additions to capitalized internal-use software	(2,415)	(674)	(948)
Additions to demonstration and bundled equipment	(6,778)	(6,971)	(4,993)
<b>Net cash used in investing activities</b>	<b>(482,222)</b>	<b>(41,053)</b>	<b>(22,087)</b>
<b>Cash flows from financing activities</b>			
Proceeds from issuance of convertible senior subordinated notes	350,000	140,000	
Proceeds from issuance of senior subordinated notes			197,194
Long-term debt borrowings	250,000	22,376	108,363
Repayment of long-term debt	(149,243)	(205,000)	(136,363)
Financing related costs	(16,553)	(7,316)	(10,274)
Proceeds from issuance of common stock	7,992	5,958	
Net proceeds from settlement of interest rate swaps		582	5,637

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Dividend and distributions to Allergan, Inc., net of advances			(196,710)
Purchase of treasury stock	(8)	(120)	(13)
	<u>          </u>	<u>          </u>	<u>          </u>
Net cash provided by (used in) financing activities	442,188	(43,520)	(32,166)
Effect of exchange rates on cash and equivalents	3,717	2,123	966
	<u>          </u>	<u>          </u>	<u>          </u>
Net increase (decrease) in cash and equivalents	3,351	(34,474)	73,621
Cash and equivalents at beginning of year	46,104	80,578	6,957
	<u>          </u>	<u>          </u>	<u>          </u>
Cash and equivalents at end of year	\$ 49,455	\$ 46,104	\$ 80,578
	<u>          </u>	<u>          </u>	<u>          </u>
<b>Supplemental disclosure of cash flow information</b>			
Cash paid during the year for:			
Interest	\$ 21,472	\$ 23,391	\$ 3,790
Income taxes	14,225	13,727	3,240
	<u>          </u>	<u>          </u>	<u>          </u>
Non-cash financing activity - Exchange of convertible notes into common stock	\$ 131,400	\$	\$
	<u>          </u>	<u>          </u>	<u>          </u>

See accompanying notes to consolidated financial statements.

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**ADVANCED MEDICAL OPTICS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**December 31, 2004, 2003 and 2002**

**Note 1: Description of Business**

AMO develops, manufactures and markets surgical devices for the eyes, with a focus on devices that are used to perform cataract surgery, a surgery in which the natural focusing lens of the eye, having become hard and clouded, is broken up and removed and subsequently replaced with an artificial lens. The Company also offers a broad range of eye care products for use with virtually all available types of contact lens. These products include disinfecting solutions to destroy harmful microorganisms in and on the surface of contact lenses, daily cleaners to remove undesirable film and deposits from contact lenses, enzymatic cleaners to remove protein deposits from contact lenses and lens rewetting drops to provide added wearing comfort.

The Company has operations in approximately 20 countries and sells its products in approximately 60 countries. On June 29, 2002, Allergan transferred its optical medical device business consisting of the ophthalmic surgical and eye care product lines to the Company in connection with a tax-free spin-off. Allergan distributed 28,723,512 shares of AMO on June 29, 2002 to Allergan stockholders of record on June 14, 2002 by means of a tax-free dividend. The spin-off resulted in AMO operating as an independent entity with publicly traded common stock. Unless the context indicates otherwise, references to the Company and AMO refer to Allergan's optical medical device business for periods prior to June 29, 2002 and to AMO and its subsidiaries for the periods on or after such date.

Allergan has no ownership interest in AMO after June 29, 2002, but performs certain services for AMO pursuant to various agreements that are outlined in Note 7. However, unless released by third parties, Allergan may remain liable for certain obligations and liabilities that were transferred to and assumed by AMO. The Company is obligated to indemnify Allergan for liabilities related to those transferred obligations and liabilities.

No annual earnings per share data for the year ended December 31, 2002 is presented as the Company's earnings were part of Allergan's earnings through the close of business on June 28, 2002.

**Note 2: Summary of Significant Accounting Policies**

This summary of significant accounting policies is presented to assist the reader in understanding and evaluating the consolidated financial statements. These policies are in conformity with accounting principles generally accepted in the United States of America and have been applied consistently in all material respects. The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements, the reported amounts of revenues and expenses during the reporting period, and related disclosures. Actual results could differ from those estimates.

***Basis of Presentation***

The consolidated financial statements include the accounts of AMO and all of its subsidiaries. All significant transactions among the consolidated entities have been eliminated from the consolidated financial statements.

Prior to the spin-off, Allergan did not account for the business that comprises AMO on the basis of separate legal entities, subsidiaries, divisions or segments. The accompanying consolidated financial statement for the year ended December 31, 2002 (through June 28, 2002) includes those revenues and expenses directly attributable to AMO's operations and allocations of certain Allergan corporate expenses to AMO. These amounts have been allocated to AMO on the basis that was considered by Allergan management to reflect most fairly or reasonably the utilization of the services provided to or the benefit obtained by the Company. The financial information included herein does not necessarily reflect what the results of operations of the Company would have been had it operated as a stand-alone public entity during all pre spin-off periods presented, and may not be indicative of future operations or financial position.

Certain reclassification of prior year amounts have been made to conform with current year presentation.

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**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

***Foreign Currency Translation***

The financial position and results of operations of AMO's foreign operations are generally determined using local currency as the functional currency. Assets and liabilities of these operations are translated at the exchange rate in effect at each year-end. Income statement accounts are translated at the average rate of exchange prevailing during the year. Translation adjustments arising from the use of differing exchange rates from period to period are included in accumulated other comprehensive income in stockholders' equity. Gains and losses resulting from foreign currency transactions and remeasurements relating to foreign operations deemed to be operating in U.S. dollar functional currency are included in "Other, net" in the accompanying consolidated statements of operations.

***Cash and Equivalents***

The Company considers cash and equivalents to include cash in banks, money market mutual funds and time deposits with financial institutions with original maturities of 90 days or less.

***Investments***

The Company has non-marketable equity investments in conjunction with its various collaboration arrangements. The non-marketable equity investments are recorded at cost and are evaluated periodically for other than temporary declines in fair value. The company uses the following criteria to determine if such a decline should be considered other than temporary:

the duration and extent to which the market value has been less than cost;

the financial condition and near-term prospects of the investee;

the reasons for the decline in market value;

the investee's performance against product development milestones; and

the Company's ability and intent to hold the investment for a period of time sufficient to allow for any anticipated recovery in market value.

If it is determined that a decline of any investment is other than temporary, then the carrying value would be written down to fair value, and the write-down would be included in earnings as a loss.



During 2002, the Company determined that the decline in fair value of two non-marketable equity investments was other than temporary. Accordingly, the Company recorded a loss of \$3.9 million.

### ***Inventories***

Inventories are valued at the lower of first-in, first-out cost or market. On a regular basis, the Company evaluates its inventory balances for excess quantities and obsolescence by analyzing demand, inventory on hand, sales levels and other information. Based on these evaluations, inventory balances are reduced, if necessary.

### ***Property, Plant and Equipment***

Property, plant and equipment are stated at cost. Additions, major renewals and improvements are capitalized, while maintenance and repairs are expensed. For financial reporting purposes, depreciation is generally provided on the straight-line method over the useful lives of the related assets, which are 20 to 40 years for buildings and improvements and from 3 to 15 years for machinery and equipment. Leasehold improvements are amortized over the life of the related facility lease or the asset, whichever is shorter. Accelerated depreciation methods are generally used for income tax purposes.

### ***Goodwill and Long-Lived Assets***

Goodwill represents the excess of acquisition costs over the fair value of net assets of purchased businesses. Intangibles include licensing agreements, trademarks and technology rights and are amortized over their estimated useful lives ranging from 3 to 13.5 years.

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**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

On January 1, 2002, the Company adopted Statement of Financial Accounting Standards No. 142, *Goodwill and Other Intangible Assets*, whereby goodwill is no longer amortized, but instead is subject to a periodic impairment review performed during the second quarter of each fiscal year. In a business combination, goodwill is allocated to the Company's various reporting units, which are the same as the Company's reportable operating segments based on relative fair value of the assets acquired and liabilities assumed. As the Company's operations are composed of four reporting units (Americas, Europe/Africa/Middle East, Japan and Asia Pacific), the Company reviews the recoverability of its goodwill by comparing each unit's fair value to the net book value of its assets. If the book value of the reporting unit's assets exceeds its fair value, the goodwill is written down to its implied fair value.

Additionally, the Company reviews the carrying amount of goodwill whenever events and circumstances indicate that the carrying amount of goodwill may not be recoverable. Impairment indicators include, among other conditions, cash flow deficits, historic or anticipated declines in revenue or operating profit and adverse legal or regulatory developments. If it is determined that such indicators are present and the review indicates that goodwill will not be fully recoverable, based upon discounted estimated cash flows, the carrying value is reduced to estimated fair market value. Estimated fair market value is determined primarily using the anticipated cash flows discounted at a rate commensurate with the risk involved.

In the second quarters of 2004, 2003 and 2002, the Company performed its annual impairment tests of its goodwill, and no impairment was indicated based on these tests.

In accordance with Statement of Financial Accounting Standards No. 144 *Accounting for the Impairment or Disposal of Long-lived Assets*, the Company assesses potential impairment to its long-lived assets when events or changes in circumstances indicate that the carrying amount of an asset may not be fully recoverable. If required, an impairment loss is recognized as the difference between the carrying value and the fair value of the assets.

***Capitalized Software***

The Company capitalizes certain internal-use computer software costs after technological feasibility has been established. These capitalized costs are amortized utilizing the straight-line method over their estimated economic life not to exceed three years.

***Demonstration (Demo) and Bundled Equipment***

In the normal course of business, the Company maintains demo and bundled equipment, primarily phacoemulsification and microkeratome surgical equipment, for the purpose and intent of selling similar equipment or related products to the customer in the future. Demo and bundled equipment are not held for sale and are recorded as other non-current assets. The assets are amortized utilizing the straight-line method over their estimated economic life not to exceed three years.

*Revenue Recognition and Accounts Receivable*

Revenue is realized or realizable and earned when persuasive evidence of an arrangement exists, delivery has occurred, the price to the buyer is determinable and collectibility is reasonably assured. We record revenue from product sales when title and risk of ownership has been transferred to the customer, which is typically upon delivery to the customer, with the exception of intraocular lenses distributed on a consignment basis, which is upon notification of implantation in a patient.

The Company generally permits returns of product if such product is returned in a timely matter, in good condition, and through the normal channels of distribution. Return policies in certain international markets can be more stringent and are based on the terms of contractual agreements with the customers. Allowances for returns are provided for based upon an analysis of our historical patterns of returns matched against the sales from which they originated. To date, historical product returns have been within the Company's estimates.

When the Company recognizes revenue from the sale of products, certain allowances known and estimable at time of sale are recorded as a reduction to sales. These items include cash discounts, allowances and rebates. These items are reflected as a reduction to accounts receivable to the extent the customer will or is expected to reduce its payment on the related invoice amounts. In addition, certain items such as rebates provided to customers that meet certain buying targets are paid to the customer subsequent to customer payment. Thus, such amounts are recorded as accrued liabilities. These provisions are estimated based on historical payment experience, historical relationship to revenues and estimated customer inventory levels. To date, historical sales allowances have been within the Company's estimates.

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**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

The allowance for doubtful accounts is determined by analyzing specific customer accounts and assessing the risk of uncollectibility based on insolvency, disputes or other collection issues. In addition, the Company routinely analyzes the different aging categories and establishes allowances based on the length of time receivables are past due.

***Concentration of Credit Risk***

Financial instruments that potentially subject the Company to credit risk principally consist of trade receivables. Wholesale distributors, major retail chains, and managed care organizations account for a substantial portion of trade receivables. This risk is limited due to the large number of customers comprising the Company's customer base, and their geographic dispersion. Ongoing credit evaluations of customers' financial condition are performed and, generally, no collateral is required. The Company maintains reserves for potential credit losses and such losses, in the aggregate, have not exceeded management's expectations.

***Income Taxes***

The Company records income taxes under the asset and liability method, whereby deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases, and for operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. Management evaluates the need to establish a valuation allowance for deferred tax assets based upon the amount of existing temporary differences, the period in which they are expected to be recovered and expected levels of taxable income. A valuation allowance to reduce deferred tax assets is established when it is more likely than not that some or all of the deferred tax assets will not be realized.

Prior to the spin-off, AMO's operations were included in Allergan's consolidated U.S. federal and state income tax returns and in the tax returns of certain Allergan foreign subsidiaries. The provision for income taxes prior to the spin-off had been determined as if AMO had filed separate tax returns under its existing structure for the periods presented. Accordingly, the effective tax rate of AMO in future years could vary from its historical effective tax rates depending on AMO's future legal structure and tax elections.

In preparing its consolidated financial statements, the Company is required to estimate its income taxes in each jurisdiction in which it operates. This process involves estimating the current liability as well as assessing temporary differences resulting from differing treatment of items for tax and financial accounting purposes. Significant management judgment is required in determining the provision for income taxes and deferred tax assets and liabilities.

The stated effective tax rate could be materially affected in the event the actual tax results differ from these estimates or if the Company adjusts these estimates in future periods.

*Stock-Based Compensation*

The Company measures stock-based compensation for option grants to employees and members of the board of directors using the intrinsic value method. The fair value of each option grant for determining the pro forma impact of stock-based compensation expense is estimated on the date of grant using the Black-Scholes option-pricing model with weighted average assumptions. These assumptions consist of expected dividend yield, expected volatility, risk-free interest rate and expected life.

**Table of Contents****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

Had compensation expense for the Company's stock options and employee stock purchase plans been recognized based upon the fair value of awards granted, the Company's net earnings (loss) would have been decreased (increased) to the following pro forma amounts (in thousands, except per share data):

	<u>2004</u>	<u>2003</u>	<u>2002</u>
<b>Net earnings (loss):</b>			
As reported:	\$ (129,370)	\$ 10,357	\$ 25,910
Stock-based compensation expense included in reported net earnings, net of tax	99	61	
Stock-based compensation expense determined under fair value based method, net of tax	(7,117)	(4,939)	(3,248)
<b>Pro forma</b>	<u>\$ (136,338)</u>	<u>\$ 5,479</u>	<u>\$ 22,662</u>
<b>Earnings per share:</b>			
As reported:			
Basic	\$ (3.89)	\$ 0.36	
Diluted	\$ (3.89)	\$ 0.35	
<b>Pro forma:</b>			
Basic	\$ (4.10)	\$ 0.19	
Diluted	\$ (4.10)	\$ 0.18	

No earnings per share data for the year ended December 31, 2002 is presented as the Company's earnings were part of Allergan's earnings through the close of business on June 28, 2002.

The value of each option grant is estimated on the date of grant using the Black-Scholes option-pricing model with the following weighted average assumptions:

	<u>Stock Options</u>			<u>ESPP</u>		
	<u>2004</u>	<u>2003</u>	<u>2002</u>	<u>2004</u>	<u>2003</u>	<u>2002</u>
Expected dividend yield	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Expected volatility	42.3%	34.8%	42.0%	0.0%	33.9%	42.0%
Risk-free interest rate	3.8%	2.9%	3.2%	0.0%	1.1%	1.6%
Expected life (in years)	4.9	4.8	3.6	0.0%	0.5	0.5
Weighted-average fair value	\$ 14.05	\$ 4.87	\$ 4.03	\$ 14.05	\$ 3.83	\$ 2.49

***Research and Development***

Research and development costs are charged to expense when incurred.

***Acquired In-Process Research and Development***

Costs to acquire in-process research and development (IPR&D) projects and technologies which have no alternative future use and which have not reached technological feasibility at the date of acquisition are expensed as incurred (see Note 3).

***Comprehensive Income (Loss)***

Comprehensive income (loss) encompasses all changes in equity other than those with stockholders and consists of net earnings (loss), foreign currency translation adjustments and unrealized gains/losses on derivative instruments, if applicable.

***Recently Adopted and Issued Accounting Standards***

In September 2004, the Emerging Issues Task Force finalized its consensus on EITF Issue No. 04-8, The Effect of Contingently Convertible Debt on Diluted Earnings Per Share (EITF 04-8). EITF 04-8 addresses when the dilutive effect of contingently convertible debt with a market price trigger should be included in diluted earnings per share (EPS). Under EITF 04-8, the market price contingency should be ignored and these securities should be treated as non-contingent, convertible securities and always included in the diluted EPS computation. EITF 04-8 requires these securities be included in diluted EPS using either the if-converted method or the net share settlement method, depending on the conversion terms of the security. EITF 04-8 is effective for all periods ending after December 15, 2004 and is to be applied by retrospectively restating previously reported EPS. The Company irrevocably elected to cash settle the principal amount of the Notes (as defined in Note 5) and thus, the dilutive effect of the Notes was calculated under the net share settlement method. Adoption of EITF 04-8 did not have an impact on EPS for the years ended December 31, 2004 and 2003, as the impact of the Existing Notes (as defined in Note 5), which were issued in June 2003, is antidilutive.

**Table of Contents****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

In November 2004, Statement of Financial Accounting Standards No. 151, *Inventory Costs*-an amendment of ARB No. 43, Chapter 4 (SFAS No. 151), was issued. This Statement amends the guidance in ARB No. 43, Chapter 4, *Inventory Pricing*, to clarify the accounting for abnormal amounts of idle facility expense, freight, handling costs, and wasted material (spoilage). SFAS No. 151 is effective for inventory costs incurred during fiscal years beginning after June 15, 2005. The Company does not expect adoption of this standard to have a material impact on its consolidated financial statements.

In December 2004, the Financial Accounting Standards Board issued a revision of Statement of Financial Accounting Standards No. 123, *Accounting for Stock-Based Compensation* (SFAS No. 123R). SFAS No. 123R supersedes APB Opinion No. 25, *Accounting for Stock Issued to Employees*, and its related implementation guidance and eliminates the alternative to use Opinion 25's intrinsic value method of accounting that was provided in Statement 123 as originally issued. Under Opinion 25, issuing stock options to employees generally resulted in recognition of no compensation cost. SFAS No. 123R requires entities to recognize the cost of employee services received in exchange for awards of equity instruments based on the grant-date fair value of those awards (with limited exceptions). SFAS No. 123R is effective for the first interim or annual reporting period that begins after June 15, 2005. The Company has not quantified the potential effect of adoption of SFAS No. 123R. However, the Company believes adoption of SFAS No. 123R will result in a decrease to reported earnings.

**Note 3: Acquisition of Pfizer Inc. Surgical Ophthalmic Business**

On June 26, 2004, pursuant to a stock and asset purchase agreement dated as of April 21, 2004, the Company completed the purchase of Pfizer Inc.'s surgical ophthalmic business for \$450 million in cash (Acquisition). Pfizer's surgical ophthalmic business manufactured and marketed surgical devices for the eyes. The Company acquired ophthalmic surgical products and certain manufacturing and research and development facilities located in Uppsala, Sweden, Groningen, Netherlands and Bangalore, India. The products acquired include the Healon line of viscoelastic products used in ocular surgery, the *CeeOn* and *Tecnis* intraocular lenses and the Baerveldt glaucoma shunt.

The primary reason for the Acquisition is to strengthen the Company's position in the global ophthalmic surgical industry by expanding its product portfolio and its manufacturing and research and development expertise.

The Acquisition has been accounted for as a purchase business combination. Under the purchase method of accounting, the assets acquired and liabilities assumed are recorded at the date of acquisition at their respective fair values.

The results of operations of the Acquisition have been included in the accompanying consolidated statements of operations from the date of the Acquisition. The total estimated cost of the Acquisition is as follows (in thousands):

Cash consideration to Pfizer Inc.	\$ 450,000
Direct costs	7,399
Cash acquired	(690)
	<hr/>
Total purchase price	\$ 456,709



The above purchase price has been allocated based on an estimate of the fair values of assets acquired and liabilities assumed.

The purchase price has been allocated based on management's estimates as follows (in thousands):

Inventories	\$ 52,411
Other current assets	350
Property, plant and equipment	39,066
Intangible assets	135,900
In-process research and development	28,100
Goodwill	255,171
Current liabilities	(14,601)
Non-current liabilities	(655)
Non-current deferred tax liability	(39,033)
	<hr/>
Net assets acquired	\$ 456,709
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Of the \$135.9 million of acquired intangible assets, \$121.0 million was assigned to developed technology rights that have a weighted-average useful life of approximately 12.7 years and \$14.9 million was assigned to a trademark with a useful

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**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

life of approximately 13.5 years. Approximately \$11.6 million of the goodwill is expected to be deductible for tax purposes. A history of operating margins and profitability, a strong scientific employee base and a strong presence in the viscoelastic market were among the factors that contributed to a purchase price resulting in the recognition of goodwill.

The acquired goodwill has been allocated to the reportable segments as follows: Americas - \$97.3 million; Europe/Africa/Middle East - \$61.8 million; Japan - \$72.4 million; and Asia Pacific - \$23.7 million.

*In-process research and development (IPR&D)*

Approximately \$28.1 million of the purchase price represents the estimated fair value of projects that, as of the acquisition date, had not reached technological feasibility and had no alternative future use. Accordingly, this amount was immediately expensed in the consolidated statement of operations for the year ended December 31, 2004. The estimated fair value assigned to IPR&D is comprised of the following projects (in thousands):

**Value of IPR&D Acquired**