VISX INC
Form 10-K
March 15, 2004

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SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K

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

For the fiscal year ended: December 31, 2003

Commission File Number: 1-10694

VISX, Incorporated

(Exact name of Registrant as specified in its charter)

Delaware	**06-1161793**
(State or other Jurisdiction of Incorporation or Organization)	*(I.R.S. Employer Identification Number)*

3400 Central Expressway

Santa Clara, California 95051
(Address of Principal Executive Offices)

(408) 733-2020

(Registrant s Telephone Number, including Area Code)

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

Common Stock, $0.01 Par Value **Common Stock Purchase Rights** *(Title of Class)*	**New York Stock Exchange** *(Name of Exchange on Which Registered)*

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 þ No o

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

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates computed by reference to the price at which the common equity was last sold, or the average bid and asked price of such common equity, as of the last business day of the registrant most recently completed second fiscal quarter was $832,000,000. Shares of common stock held by each executive officer, director, and each person who beneficially owns 5% or more of the outstanding common stock, have been excluded because such persons may, under certain circumstances, be deemed to be affiliates. The determination of an affiliate or an executive officer status is not necessarily conclusive for other purposes.

The number of Common Shares outstanding as of February 24, 2004 was 48,624,823.

DOCUMENTS INCORPORATED BY REFERENCE

Certain portions of the registrant s Proxy Statement for its Annual Meeting of Stockholders to be held in 2004 are incorporated by reference into Part III.

VISX, INCORPORATED

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NOTE: VISX, VISX STAR, VISXPRESS, VISX STAR 2, VISX STAR S3, STAR S2, STAR S3, VISX STAR S4, STAR S4, VISX STAR S3 ActiveTrak, VISX University, CustomVue, PreVue, CUSTOM-CAP, VSS, VisionKey, WaveScan, and WaveScan WaveFront are trademarks of VISX, Incorporated.

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This report contains forward-looking statements that involve risks and uncertainties. Our actual results may differ significantly from the results contemplated by the forward-looking statements. Please carefully review and consider the sections of this report under the headings, *Legal Proceedings* and *Risk Factors* in addition to the other information presented in this report, for a description of the risks and uncertainties facing our business.

PART I

Item 1. *Business*
The Company

VISX, Incorporated (VISX), a Delaware corporation organized in 1988, is a leader in the design and development of proprietary technologies and systems for laser vision correction. We sell products worldwide and generate the majority of our revenue through the sale of treatment cards that are required to perform laser vision correction procedures on the VISX STAR™ Excimer Laser System (VISX STAR System). We have also licensed our technology to other excimer laser system companies and generally receive royalties for the sale of their systems or for procedures that are performed in the United States using their systems.

According to MarketScope, a refractive surgery market research group, 50% to 60% of the population in North America, Western Europe and parts of the Asian Pacific region requires some type of vision correction. In the United States alone there are 50 to 60 million laser vision correction candidates who experience some form of nearsightedness, farsightedness, or astigmatism. To date, the industry has penetrated less than 6% of the United States population eligible for refractive surgery.

We have developed and continue to refine a substantial proprietary position in system and application technology relating to the use of lasers for vision correction. Our strategy is to directly apply existing and new proprietary technologies to the advancement of systems for vision correction and to acquire technologies and products that enable us to expand our presence in the refractive surgery market.

Refractive Vision Disorders

The human eye functions much like a camera. It incorporates a lens system that focuses light (the cornea and the lens), a variable aperture system that regulates the amount of light passing through the eye (the iris), and film that records the image (the retina). In a properly functioning eye, entering light is refracted by the cornea and lens, causing the image to focus on the retina. The retina translates the image into an electrical signal, which it relays to the optic nerve and from there to the brain.

In a refractive vision disorder, the cornea is improperly curved and cannot properly focus (or refract) light passing through it onto the retina. As a result, the image is blurred. The three refractive vision disorders most commonly treated today are:

Nearsightedness (also known as myopia): images are focused in front of the retina; and

Farsightedness (also known as hyperopia): images are focused behind the retina; and

Astigmatism: images are not focused at any one point on the retina.

Currently, eyeglasses or contact lenses are most often used to correct these vision disorders.

In addition to these refractive vision disorders, eyeglasses are often used to correct a vision disorder known as *presbyopia*, a condition in which images are not focused at close range due to age-related loss of accommodation by the lens of the eye.

Other vision disorders, known as higher order aberrations, can also result in blurred vision. Higher order aberrations cannot currently be corrected with eyeglasses or contact lenses and, until recently, were not measurable. Recent technological advances enable treatment of these higher order aberrations with laser vision correction.

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Laser Vision Correction

Laser Vision Correction (sometimes abbreviated as LVC) eliminates or reduces reliance on eyeglasses or contact lenses. It employs a computerized laser that ablates, or removes, sub-micron layers of tissue from the surface of the cornea, reshaping the eye and thereby improving vision.

The VISX STAR System employs an excimer laser that ablates tissue without generating the heat that can cause unintended thermal damage to surrounding tissue. The excimer laser operates in the ultraviolet spectrum and acts on the surface of the cornea; light from the laser does not penetrate the eye, so there is no measurable effect in the interior of the eye.

The pulses of laser light ablate submicron layers of tissue from the surface of the cornea in a pattern to reshape the cornea. A micron equals 0.001 of a millimeter, and the depth of tissue ablated during the procedure typically is less than the width of a strand of human hair. The average procedure lasts approximately 15 to 40 seconds and consists of approximately 150 laser pulses, each of which lasts several billionths of a second. The cumulative exposure of the eye to laser light is less than one second. The entire patient visit, including preparation, application of a topical anesthetic, and post-operative dressing, generally lasts about 30 minutes when LVC is performed using the VISX STAR System.

LASIK

Laser Assisted *In Situ* Keratomileusis (LASIK) is the most common method for performing LVC. To perform LASIK, a device called a microkeratome is typically used to create a thin flap on the cornea. The ophthalmologist folds back the flap, ablates the exposed corneal surface with the laser, and then returns the flap to its original position. LASIK has gained in popularity primarily because there is minimal postoperative discomfort and an almost immediate improvement in uncorrected vision (vision without the aid of eyeglasses or contact lenses). Nevertheless, LASIK requires a high degree of surgical skill and can result in adverse events, often attributable to the microkeratome.

Standard LASIK

Standard LASIK was introduced in the mid 1990 s. In performing Standard LASIK, an ophthalmologist conducts a traditional eye examination and determines the prescription required to correct the patient s vision. The prescription is then programmed into the VISX STAR System which calculates the ablation needed to make a precise corneal correction to treat nearsightedness, farsightedness, and astigmatism. Unlike Custom LASIK (see below), Standard LASIK cannot correct higher order aberrations.

Custom LASIK

The most advanced method of performing laser vision correction is Custom LASIK. Custom LASIK employs a diagnostic evaluation of the eye that measures refractive errors in the patient s vision more precisely than previously available technology. VISX s Custom LASIK, known as CustomVue™ laser vision correction, uses the VISX WaveScan WaveFront® System (WaveScan® System) to obtain comprehensive information about the imperfections, or refractive errors, of each patient s vision. Refractive errors are displayed by the WaveScan System in the form of an aberration map that offers a unique pattern for each person s eye, similar to a fingerprint. The map displays information about refractive errors that result in nearsightedness, farsightedness, and astigmatism, as well as information about higher order aberrations that were not previously measurable by any other instrument.

The information from the WaveScan System is used to generate a personalized treatment plan that is digitally transferred to the VISX STAR System. The ablation derived from this information is therefore customized to the individual s eye. Because CustomVue laser vision correction can correct visual errors that were previously not measurable, it has the potential to improve vision beyond corrections obtained with contacts or glasses. VISX clinical data, reported at the American Society of Cataract and Refractive Surgeons (ASCRS) in April 2003, show that patients treated with CustomVue laser vision correction experienced considerable improvement in vision and generally were more satisfied with night vision compared with their preoperative vision.

VISX introduced CustomVue laser vision correction internationally in late 2002 and received United States Food and Drug Administration (FDA) approval for CustomVue vision correction in the U.S for the treatment of myopia and astigmatism in May 2003.

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PRK

Laser vision correction can also be performed by photorefractive keratectomy (PRK). PRK does not require the use of a microkeratome, and in most procedures the epithelial layer (or outer layer) of the cornea is removed before ablation. Patients may experience discomfort for approximately 24 hours and blurred vision for approximately 48 to 72 hours after the procedure. Drops to promote corneal healing and alleviate discomfort may be prescribed. Although most patients experience significant improvement in uncorrected vision (vision without the aid of eyeglasses or contact lenses) within a few days of the procedure, unlike LASIK it generally takes several months for the final correction to stabilize and for the full benefit of the procedure to be realized.

The VISX STAR System performs PRK in essentially the same manner as Standard LASIK.

Corneal Pathologies: Custom-CAP® and PTK

VISX offers additional capabilities to ophthalmologists to enable treatment of corneal pathologies which are limited in number but provide potential relief to patients with essentially no alternative treatment. Our Custom-CAP procedure treats patients who previously had laser vision correction surgery resulting in symptomatic decentered ablations. We have been granted a Humanitarian Device Exemption by the FDA for this treatment, which allows the use and marketing of a device that is intended to benefit patients in the treatment of conditions that affect fewer than 4,000 individuals per year.

The VISX STAR System also treats certain types of corneal pathologies known as PhotoTherapeutic Keratectomy (PTK). Our PTK procedure treats corneas that are scarred or have irregularities from prior infection, trauma, or underlying corneal disease. We estimate that VISX STAR Systems have been used worldwide to perform approximately 35,000 PTK procedures.

Although both Custom-CAP and PTK are important medical procedures for people who suffer from corneal pathologies, the market opportunity represented by Custom-CAP and PTK is much smaller than that represented by laser vision correction in general.

FDA Approvals

In 1987, ophthalmologists used VISX® equipment to perform the first laser vision correction procedure for the treatment of nearsightedness in the United States. In 1996, the FDA approved laser vision correction using the VISX STAR System. Since that time, VISX has expanded the capabilities of its system to treat a broader range of refractive errors.

To date, the FDA has approved the following treatments using the VISX STAR System:

FDA Treatment Approval	
	FDA Approval Date
Myopia or near sightedness	March 1996
Astigmatism	April 1997
Higher myopia with or without astigmatism	January 1998
Hyperopia or farsightedness	November 1998
Laser Assisted *In Situ* Keratomileusis (LASIK)	November 1999
WaveScan System to diagnose refractive errors of the eye	May 2000, received 510(k) clearance
Enlarged treatment zone with a blended ablation edge	March 2001

Mixed astigmatism	November 2001
Custom-Contoured Ablation Patterns (Custom-CAP™ Method) for the treatment of patients with symptomatic decentered ablations from previous laser surgery	December 2001, under the Humanitarian Device Exemption program (HDE)
CustomVue for myopia and astigmatism	May 2003

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International Approvals

VISX has received regulatory approvals where applicable in essentially all international markets.

Products

VISX STAR Excimer Laser System. The VISX STAR System is a fully integrated ophthalmic medical device incorporating an excimer laser and a computer-driven workstation. The laser ablations produced by the VISX STAR System are the product of a variable diameter excimer laser beam scanning system. Seven beams that range in size from 0.65 to 6.5 millimeters are homogenized as they converge, scan, and rotate to produce an extremely smooth ablation area on the eye.

Only the VISX STAR System is capable of performing treatments using a multi-variable sized scanning beam (which includes small-spot scanning) commonly known as variable spot scanning, or VSS™. This enables refractive corrections to be completed in a shorter time and with less tissue removal than with other excimer lasers. In addition, the VISX STAR System centers on the eye and tracks eye movements in three dimensions during the procedure. This ensures precisely centered ablations and adds another element of safety and comfort for both patient and doctor.

The VISX STAR System performs Standard LASIK, CustomVue laser vision correction, PRK, Custom-CAP, and PTK procedures.

VISX WaveScan System. The WaveScan System is a diagnostic device that uses laser beam technology to measure comprehensive refractive errors of the eye and complex mathematical algorithms to derive comprehensive refractive information about the patient s individual optical system, and then displays this information in the form of an aberration map. This unique map, similar to a fingerprint for each patient s eye, offers objective information about refractive errors associated with nearsightedness, farsightedness, and astigmatism, as well as information about higher order aberrations that were previously unmeasurable by any other instrument.

VISX Treatment Cards. We control the use of the VISX STAR System with proprietary cards. Each card provides the user with specific access to proprietary software and is required to operate the VISX STAR System. Because treatment cards are required to perform procedures, there is a strong correlation between treatment card sales and the number of procedures performed on VISX STAR Systems. Types of VISX treatment cards include: VisionKey® Cards for performing standard LASIK procedures, which in the United States carries a license fee for each procedure that is purchased; CustomVue Cards for performing Custom LASIK, which carry a worldwide license fee for each procedure that is purchased; Custom-CAP Cards for performing laser vision correction with a previously decentered ablation, which carry a worldwide license fee for each procedure that is purchased; and the PTK Card, which is offered to physicians at a nominal charge to treat certain types of corneal pathologies.

Information concerning the amount and percentage of revenues contributed by our different products and services is set forth later in this report under the heading, Management s Discussion and Analysis of Financial Condition and Results of Operations.

Marketing, Sales and Distribution

Our primary objective is to maximize consumer acceptance of laser vision correction by (a) providing advanced diagnostic and laser technology to the eye care medical community, (b) developing improvements to that technology, and (c) providing our customers with various services and programs designed to increase their operating efficiency, effectiveness, and volume of laser vision correction procedures.

In the United States, we sell products directly to our customers and employ sales and service engineers to support our business. In 2002 we established VISX USA, Inc., a wholly owned subsidiary, to which we transferred our United States sales and marketing assets in 2003. Internationally, our systems are installed in 46 countries. We have established a subsidiary in Japan and have sales managers that cover key international sales regions. We have contracts with more than 36 distributors worldwide that are responsible for selling and servicing VISX products internationally.

Marketing Programs

We believe that ongoing support and training of customers has enhanced our market position. The programs listed below are offered to VISX customers in the United States. We are expanding some of these programs to international markets.

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VISX University® Programs. VISX University is a series of educational programs designed to educate physicians, administrators, coordinators, and technicians on current practices in laser vision correction and to teach laser center decision-makers how to effectively manage and market their laser vision correction practices.

VISX University Refractive Society Symposiums are continuing medical education (CME) accredited events, typically held in conjunction with major ophthalmic and optometric meetings, drawing speakers from around the world to share their experiences on the latest refractive techniques and technologies. Refractive surgeons are encouraged to attend these events to obtain important information about the latest VISX technology and updates on the development of new technologies.

VISX University Practice Development Seminars feature a two-day program of small group, interactive workshops in which participants learn about the experiences of successful VISX laser vision correction marketers and share their own experiences. These workshops provide VISX customers with the opportunity to benefit from marketing and management instruction regarding successful laser vision correction practices. Attendees learn about procedure-building techniques in advertising, marketing, public relations, lead tracking, staff training, consumer education and recruitment.

In addition to VISX University Programs, customers who buy or use a VISX STAR System are provided educational and marketing materials including brochures, videos, slides, and other tools to help them promote VISX laser vision correction.

VISX Business Development Program. VISX employs a team of industry experts known as Business Development Managers who have geographical account responsibility across the United States. Each Business Development Manager is responsible for providing the instruction, information and services necessary to help our customers maximize their investment in VISX products and services. Customers that participate in this program receive intensive hands on consulting and training to help them increase the number of laser vision correction procedures they perform. This consulting includes development of a plan that identifies specific areas to be modified so the customer can respond more effectively to consumers interested in having laser vision correction on a VISX STAR System.

Procedure Financing Support Program. We refer our customers to several financial vendors that provide consumer financing to patients through eye care professionals. This enables ophthalmologists to offer consumers the option of paying for their laser vision correction procedure on a monthly basis. We are not directly involved with these financing programs and do not benefit from the financing except to the extent it contributes to growth in the number of laser vision correction procedures performed.

Customer Support and Service

Customer Response Center. The VISX Customer Response Center handles customer calls 24 hours a day, seven days a week, and is staffed by over 80 VISX professionals trained to respond to calls and inquiries from our customers. Telephone requests range from orders for parts and treatment cards to requests for technical support, customer information and field service. More than 60 members of the Customer Response Center are field-based service engineers, strategically located to enable rapid response to customer needs.

VISXPRESS®. We communicate the latest news regarding VISX and laser vision correction through a publication called VISXPRESS. The frequency of the publication is determined by the timing of news.

VISX on the Internet. The Internet s interactive capabilities enhance the effectiveness of communications with customers and the professional eye care community at large. Our website, at **http://www.visx.com,** includes the following resources:

Information for consumers regarding the benefits of VISX laser vision correction, including an interactive map providing consumers with the locations of VISX installations and VISX-certified physicians;

Clinical information for the physician community, including downloadable presentations and white papers concerning the most recent VISX clinical results from leading ophthalmologists worldwide;

On-line access to news about new products and services, physician certification course schedules, and registration for practice development programs such as VISX University; and

Marketing and practice development tools, including links to services and web sites that provide useful information for promotion of laser vision correction by our physicians.

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Major Customers

TLC Vision Corporation (TLC) accounted for 16%, 14%, and 17% of total revenues in 2003, 2002, and 2001, respectively. No other customer accounted for 10% or more of sales during any of the three years ended December 31, 2003.

Reliance on Patents and Proprietary Technology

We own over 200 United States and foreign patents and have more than 200 patent applications pending. We believe our patents provide a substantial proprietary position in system and application technology relating to the use of lasers for vision correction. We are committed to protecting our proprietary technology. It is possible, however, that one or more of our patents may be found to be invalid or unenforceable, or that a party against whom we are asserting claims of patent infringement may be found not to be infringing our patents. Such an outcome could have a material adverse effect on our business, financial position, and results of operation. Please see *Risk Factors/Patents and Intellectual Property Disputes* below for additional discussion of the risks related to our intellectual property.

Cross License between VISX and Nidek. On April 4, 2003, VISX and Nidek entered into a global litigation settlement and a worldwide cross-license of certain of the parties respective patents. This settlement resulted in the dismissal of all litigation between the parties worldwide, and involved a payment by VISX to Nidek of $9.0 million for the settlement of Nidek s antitrust and unfair competition claims. The terms of the settlement and cross-license are confidential.

License to WaveLight. In September 2002, VISX and WaveLight Laser Technologie AG (WaveLight) signed an agreement whereby we licensed our patents relating to refractive excimer lasers to WaveLight. As consideration, WaveLight will pay VISX a royalty for each procedure performed in the United States using WaveLight s refractive excimer laser and for international equipment sales. All pending disputes and litigation between the two companies were also settled at that time.

License to LaserSight. In May 2001, VISX and LaserSight Incorporated (LaserSight) signed an agreement whereby we licensed our patents relating to refractive excimer lasers to LaserSight. As consideration, LaserSight will pay VISX a royalty for each procedure performed in the United States using LaserSight s refractive excimer laser. All pending disputes and litigation between the two companies were also settled at that time.

In May 2002, LaserSight granted VISX a worldwide, royalty-free, fully paid-up, nonexclusive license under United States Patent No. RE37,504 (5,520,697 JT Lin Patent).

Cross License between VISX and Bausch & Lomb. In January 2001, VISX and Bausch & Lomb signed an agreement whereby we licensed our patents relating to refractive excimer lasers to Bausch & Lomb. As consideration, Bausch & Lomb licensed its patents relating to refractive excimer lasers to us and will pay us a royalty for each procedure performed in the United States using Bausch & Lomb s refractive excimer laser. All pending disputes and litigation between the two companies were also settled at that time.

Cross License between VISX and Summit. In June 1998, VISX and Summit Technology, Inc. (Summit), now owned by Alcon, signed an agreement whereby VISX and Summit each granted the other a fully-paid license to its patents relating to laser ablation of corneal tissue. The licenses cover, with certain exceptions, technology acquired by the recipient of the license. At that time, we dissolved Pillar Point Partners and settled all pending disputes and litigation between the two companies.

Non-United States Licensing Agreements. We have licensed certain patents issued outside of the United States to the following companies: Chiron Vision Corporation, now owned by Bausch & Lomb, Zeiss-Meditec GmbH (Zeiss-Meditec), Herbert Schwind GmbH & Co. KG (Schwind), Autonomous Technologies Corporation (Autonomous), previously owned by Summit and now owned by Alcon, LaserSight, and WaveLight. Under these agreements, we receive royalties for international sales of Bausch & Lomb, Zeiss-Meditec, Schwind, LaserSight, and WaveLight equipment that is covered by our international patents. In addition, Summit has taken a fully paid license to our non-United States patents, which covers sales of the Summit and Autonomous laser systems.

In 1992, International Business Machines Corporation (IBM) granted VISX nonexclusive rights under United States and foreign IBM patents that include certain claims covering ultraviolet laser technology for removal of human tissue. Under the terms of this license, we agreed to pay a royalty on VISX STAR Systems made, used, sold or otherwise transferred by or for VISX in the United States and certain other countries. In 1997, IBM advised us that it assigned the patents and the license to LaserSight. In February 1998, LaserSight advised us that Nidek had acquired the foreign IBM

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patents and the licenses to these foreign patents. As part of the agreement entered into by VISX and LaserSight in May 2001, we obtained a paid-up license to the United States IBM patent. We also entered into a nonexclusive, worldwide license agreement with Patlex Corporation (Patlex), which holds certain patents on lasers. Under this agreement, we pay Patlex a royalty on certain laser components of the VISX STAR System.

Confidentiality Arrangements. We protect our proprietary technology, in part, through proprietary information and inventions agreements with employees, consultants and other parties. These agreements generally contain standard provisions requiring those individuals to assign to VISX, without additional consideration, inventions conceived or reduced to practice by them while employed or retained by VISX, subject to customary exceptions.

Government Regulation

United States Food and Drug Administration. The VISX STAR System and WaveScan System are medical devices, and as such are subject to regulation by the FDA under the Food, Drug, and Cosmetic Act and by similar agencies outside of the United States. Products manufactured or distributed by us are subject to pervasive and continuing regulation by the FDA, including, among other things, post-market surveillance and adverse event reporting requirements. Labeling and promotional activities are subject to scrutiny by the FDA and, in certain instances, by the Federal Trade Commission.

We manufacture our products in accordance with Good Manufacturing Practices (GMP) regulations, which impose procedural and documentation requirements with respect to manufacturing and quality assurance activities. Our manufacturing facilities, procedures and practices have undergone and continue to be subject to GMP compliance inspections conducted by the FDA.

The FDA s Quality System Regulation (QSR) went into effect on June 1, 1997. The goal of QSR is to make the existing GMP regulations consistent, to the extent possible, with the requirements for quality systems contained in applicable international standards, primarily, the International Organization for Standardization (ISO) 9001:1994 Quality Systems/Model for Quality Assurance in Design, Development, Production, Installation, and Servicing. On February 3, 1998, we were certified to ISO 9001/EN46001. To ensure continuing compliance with ISO standards, we undergo annual recertification audits, the most recent of which concluded with the issuance of certificates on December 23, 2003, certifying that VISX has been assessed and registered as conforming to the requirements of ISO 9001:2000 and ISO 13485:1996. These recertification audits are carried out by registered certification agencies. We have successfully passed each annual recertification audit since our initial certification.

Other Government Regulation. We are regulated under the Radiation Control for Health and Safety Act, which requires laser products to comply with performance standards, and manufacturers to certify in product labeling and in reports to the FDA that their products comply with all such standards. In addition, we are subject to California regulations governing the manufacture of medical devices, including an annual licensing requirement, and our facilities have been inspected by, and are subject to ongoing, periodic inspections by, California regulatory authorities. Sales, manufacturing and further development of VISX products also may be subject to additional federal regulations pertaining to export controls and environmental and worker protection, as well as to state and local health, safety and other regulations that vary by locality, which may require obtaining additional permits. The impact of such regulations cannot be predicted. Our products have been tested and certified to comply with all applicable safety requirements for medical devices in the United States and Canada, and bear the ETL-c Mark as evidence of compliance.

International. Many countries outside the United States do not impose safety and efficacy testing or regulatory approval requirements for medical laser devices. International regulatory requirements vary by country, however.

In Europe, the member countries of the European Union have promulgated rules that require medical products to receive the certifications necessary to affix the CE Mark to the device. The CE Mark is an international symbol of adherence to quality assurance standards and compliance with applicable European medical device directives. Certification under the ISO standards for quality assurance and manufacturing processes is one of the CE Mark requirements. We are licensed to apply the CE Mark to the VISX STAR System and WaveScan System in accordance with the European Medical Device Directives.

In Japan, we received regulatory approval for PTK from the Japanese Ministry of Health, Labor and Welfare in May 1998 and for myopia, or nearsightedness, with astigmatism in January 2000. The Japanese Ministry of Health, Labour and Welfare approved the VISX STAR S3 ActiveTrak® System (a VISX STAR System) that includes three dimensional eye tracking on December 5, 2001. We are the only United States manufacturer to receive approval for its laser vision correction system in Japan.

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Competition

There are six companies whose excimer laser systems have received FDA approval in the United States, namely, those of VISX, Alcon, Bausch & Lomb, LaserSight, Nidek, and WaveLight. According to MarketScope VISX holds approximately 60% of the procedure volume market share and VISX STAR Systems represent over 50% of laser vision correction systems in use today in the United States.

We have licensed our technology to Bausch & Lomb, LaserSight, Nidek, and WaveLight. VISX and Alcon granted each other cross licenses to patents covering ultraviolet ablation of corneal tissue.

Our principal international competitors are Alcon, Bausch & Lomb, LaserSight, Nidek, Schwind, WaveLight, and Zeiss-Meditec. According to MarketScope, VISX holds approximately 30% of the installed base of laser vision correction systems internationally, with no other competitor exceeding this market share. We have licensed certain of our patents to Bausch & Lomb, LaserSight, Nidek, Schwind, WaveLight, and Zeiss-Meditec. In addition, Alcon has taken a royalty-free license to our non-United States patents, which covers sales of its systems.

Manufacturing, Components and Raw Materials

The manufacture of VISX STAR Systems and WaveScan Systems is a complex operation involving numerous procedures, and the completed systems must pass a series of quality control and reliability tests before shipment. We buy from various independent suppliers many components that are either standard or built to our proprietary specifications, and which are then assembled at our California facility. We also contract with third parties for the manufacture or assembly of certain components. A single vendor currently provides several of these components. Please see *Risk Factors/Single Sources for Key Components* below for a description of the risks we face due to our reliance on sole-source vendors.

Research and Development and Regulatory

Our research efforts have been the primary source of our products. We intend to maintain our strong commitment to research as an essential component of our product development effort. Toward this end, we incurred research and development expenses, including clinical trial expenses, of $18.6 million in 2003, $18.7 million in 2002, and $19.5 million in 2001. Licensed technology developed by outside parties is an additional source of potential products. In 2003, VISX continued funding the early stage research at Stanford University for future treatments for age-related macular degeneration. We are also developing an excimer laser treatment for presbyopia. We conducted clinical trials for presbyopia in human subjects in Canada during 2003.

Employees

As of December 31, 2003, we had 344 full time employees, 27 temporary employees and 19 consultants. Of our regular employees, 183 are employed in manufacturing and service, 66 in research and development and regulatory, and 95 in general administrative and marketing and sales positions. None of our employees are covered by a collective bargaining agreement. We believe that our relations with employees are good.

Seasonal Variation

Typically we experience an increase in procedure-related revenue in the United States market in the first quarter of each calendar year. We attribute this increase to consumers using the annual renewal of funding under the Internal Revenue Service Code section 125 pre-tax medical savings plan to purchase laser vision correction for themselves. Laser vision correction is not generally covered by medical insurance. Our equipment and procedure revenue tend to decline in the summer.

Financial Information about Segments and Geographic Areas

Financial information relating to VISX s segments and information on revenues generated in different geographic areas are set forth in Note 2, titled Segment Reporting, of Notes to Consolidated Financial Statements in Item 8 of this report. In addition, information regarding risks attendant to our foreign operations is set forth under the heading Risk Factors later in this report.

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Where You Can Find More Information

We make our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and all amendments to such reports filed pursuant to Section 13(a) or 15(d) of the Exchange Act, available, free of charge, on or through our Internet web site located at www.visx.com under the Investor Relations section, as soon as reasonably practicable after they are filed with or furnished to the SEC.

In addition, the written charters approved by our Board of Directors and adopted by our Audit, Compensation, and Governance committees are posted on our Internet web site located at www.visx.com under the Investor Relations section, together with our Corporate Governance Guidelines and Code of Business Conduct and Ethics. Copies of these documents will be provided at no-charge to any stockholder who requests a copy.

Item 2. ***Properties***

Our operations are currently located in a 108,844 square foot leased facility in Santa Clara, California. The lease for the facility expires in May 2008 with an option to extend the term an additional five years. We also lease approximately 25,000 square feet of warehouse space in Sunnyvale, California under a lease that expires in March 2006.

We also lease space in Osaka and Tokyo, Japan. Two leases for office space are for 871 and 1,835 square feet and expire on January 31, 2006 and September 30, 2006, respectively. Two leases for warehouse space cover 710 and 355 square feet. The first lease expires on March 31, 2004, and the second lease expires on December 31, 2004. We believe our facilities are sufficient to meet our current and reasonably anticipated future requirements. See Note 9 of Notes to Consolidated Financial Statements.

Item 3. ***Legal Proceedings***

In and prior to 2003, VISX and one of its competitors, Nidek, was involved in litigation in the United States and elsewhere relating to the parties respective patent rights and Nidek s claims that our activities violated antitrust and unfair competition laws. On April 4, 2003, VISX and Nidek entered into a global litigation settlement and a worldwide cross-license of certain of the parties respective patents. This settlement resulted in the dismissal of all litigation between the parties worldwide, and involved a payment by VISX to Nidek of $9.0 million for the settlement of Nidek s antitrust and unfair competition claims. For a complete description of this litigation, see our annual report on Form 10-K for the year ended December 31, 2002 and our quarterly report on Form 10-Q for the quarter ended March 31, 2003.

Other Litigation

We are involved in various other legal proceedings and disputes that arise in the normal course of business. These matters include product liability actions, contract disputes and other matters. Based on currently available information, we believe that we have meritorious defenses to these actions and that the resolution of these cases is not likely to have a material adverse effect on our business, financial position or future results of operations.

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

No matters were submitted to a vote of security holders during the fourth quarter of 2003.

Item 4A. ***Executive Officers of the Registrant***

Each executive officer holds his or her office for a one-year term. Our principal executive officers are:

Name	Age	Position	Year First Held Current Position
Elizabeth H. Dávila	59	Chairman of the Board and Chief Executive Officer	2001

Douglas H. Post	52	President and Chief Operating Officer	2003
Derek A. Bertocci	50	Senior Vice President, Chief Financial Officer	2004
Carol F.H. Harner, Ph.D	60	Senior Vice President, Research and Development	1997

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Name	Age	Position	Year First Held Current Position
Donald L. Fagen	50	Vice President, Global Sales	2001
Theresa A. Johnson	41	Vice President, Operations	2003
Catherine E. Murphy	56	Vice President, Human Resources	2001
John F. Runkel, Jr.	48	Vice President, General Counsel and Secretary	2001
Alan F. Russell, Ph.D.	62	Vice President, Regulatory and Clinical Affairs	2001
Joaquin V. Wolff	46	Vice President, Global Marketing	2001

Elizabeth H. Dávila. Ms. Dávila joined VISX in 1995 and currently serves as chairman of the board and chief executive officer. She was appointed chairman of the board in May 2001, and has served as chief executive officer since February 2001. She also served as president from February 2001 to July 2003. She was president and chief operating officer from February 1999 to February 2001, executive vice president and chief operating officer from May 1995 to February 1999, and served as a director since December 1995. Prior to joining VISX, Ms. Dávila was at Syntex Corporation from 1977 to 1994 where she held senior management positions in its medical device, medical diagnostics, and pharmaceutical divisions. Ms. Dávila serves on the board of directors of Nugen Technologies, Inc. and Cholestech Corporation. She holds a masters degree in chemistry from Notre Dame and an MBA from Stanford University.

Douglas H. Post. Mr. Post has served as president and chief operating officer since July 2003. He was executive vice president, operations from January 2001 to July 2003. Prior to that time he was vice president, operations and customer support from September 1996 to January 2001. He served as senior director, customer support from December 1992 to September 1996 and was senior vice president, sales & customer support, with VISX Massachusetts Inc. (formerly Questek, Inc.) from February 1985 to December 1992.

Derek A. Bertocci. Mr. Bertocci has served as senior vice president and chief financial officer since March 2004. He was vice president and controller from December 1998 to February 2004. He was controller from November 1995 to December 1998. Prior to joining VISX, Mr. Bertocci was controller for Time Warner Interactive from 1993 to 1995. From 1987 to 1993, he was controller and assistant treasurer for Datron Systems, Inc.

Carol F. H. Harner, Ph.D. Dr. Harner has been senior vice president, research and development since August, 2003. She was vice president, research and development from December 1997 to August 2003. Prior to joining VISX, she was vice president, scientific affairs of Collagen Corporation, and president of CollOptics, Inc., a subsidiary of Collagen Corporation. Before joining Collagen Corporation, Dr. Harner held senior management and scientific positions at Chiron Ophthalmics Inc. from 1986 to 1993, and CooperVision Surgical, from 1984 to 1986. Prior to that, she was in academia for 13 years.

Donald L. Fagen. Mr. Fagen has been vice president, global sales since February 2001. Prior to joining VISX, Mr. Fagen was vice president, sales and marketing for The Hillside Group from 2000 to 2001 and executive vice president, sales and marketing with ClearVision, Inc. from 1999 to 2000. From 1995 to 1999, Mr. Fagen held the position of director of sales and group purchasing organizations with Alcon Laboratories. Prior to that time, Mr. Fagen directed sales organizations at CooperVision Surgical and Sci Med from 1985 to 1995.

Theresa A. Johnson. Ms. Johnson has been vice president, operations since October 2003. She was director of materials and logistics from 1999 to 2003, manager of materials from 1994 to 1999 and held other management positions at VISX from 1988 to 1994. Prior to joining VISX, Ms. Johnson held various positions at CooperVision Laser Division, commencing in 1984.

Catherine E. Murphy. Ms. Murphy has been vice president, human resources, since September 2001. Prior to joining VISX, Ms. Murphy was director of compensation, benefits and human resource information technology for Genentech, from 1998 to 2001. From 1996 to 1998, Ms. Murphy served as a human resource consultant for a variety of medical device and biopharmaceutical firms. From 1983 to 1996, she held a variety of management positions within Syntex Corporation in the areas of compensation, benefits, employee relations, staffing and related human resource functions.

John F. Runkel, Jr. Mr. Runkel has been vice president, general counsel, and secretary since January 2001. Prior to joining VISX, Mr. Runkel was a partner in the law firm of Sheppard, Mullin, Richter & Hampton, where he practiced law for 17 years and served as managing partner of the firm s San Francisco office.

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Alan F. Russell, Ph.D. Dr. Russell has been vice president, regulatory and clinical affairs since June 2001. Prior to joining VISX, Dr. Russell was CEO of AvMax, Inc., a privately held pharmaceutical company, from 1998 to 2000. From 1992 to 1998, Dr. Russell was senior vice president, scientific affairs at Cygnus, Inc. Prior to that, he was vice president for scientific affairs at Chiron Corporation from 1987 to April 1992. He held the same position at Beecham Laboratories from 1983 to 1987, prior to which he held various management positions at Syntex Corporation from 1971 to 1983, including director of regulatory affairs for investigational drugs.

Joaquin V. Wolff. Mr. Wolff has been vice president of global marketing since January 2001. Prior to joining VISX, Mr. Wolff worked at Alcon Laboratories from 1990 to 2000, where he held the position of director of marketing with responsibilities in both the Cataract and Vitreoretinal business units of the Surgical Division. From 1983 to 1990, he held a variety of sales and marketing positions for CooperVision Surgical.

Our Board of Directors has approved the adoption by our executive officers and directors of trading plans under Securities and Exchange Commission Rule 10b5-1. A number of our executive officers and directors have adopted and are trading pursuant to Rule 10b5-1 plans.

PART II

Item 5. ***Market for VISX s Common Equity and Related Stockholder Matters***

Our common stock is traded on the New York Stock Exchange under the symbol EYE . Prior to September 7, 2000, our stock was traded on the Nasdaq National Market tier of The Nasdaq Stock Market under the symbol VISX . The following table sets forth the high and low closing prices of our common stock.

	High	Low
2002		
First Quarter	$17.70	$12.90
Second Quarter	17.80	10.90
Third Quarter	10.80	7.18
Fourth Quarter	10.27	7.38
2003		
First Quarter	$10.06	$ 7.93
Second Quarter	18.81	11.06
Third Quarter	23.28	17.74
Fourth Quarter	25.77	18.95

On February 24, 2004, the last reported sale price of the Common Stock on the New York Stock Exchange was $17.70 per share. We had approximately 725 holders of record of our common stock on that date.

We have never declared or paid any cash dividends on our common stock. We presently intend to retain all future earnings for use in our business and do not anticipate paying any cash dividends on our common stock in the foreseeable future.

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Item 6. ***Selected Financial Data***

We derived the following selected financial data from our audited consolidated financial statements. This historical financial data should be read in conjunction with our consolidated financial statements and notes thereto.

Selected Condensed Consolidated Financial Information

	Year Ended December 31,				
	(In thousands, except per share data)				
	2003	**2002**	**2001**	**2000**	**1999**
Statement Of Operations Data:					
Total revenues	$143,905	$139,926	$165,016	$190,154	$268,691
Cost of revenues	52,070	50,805	58,440	62,684	57,513
Total costs and expenses	109,300	112,056	119,844	134,162	126,593
Income from operations	34,605	27,870	45,172	55,992	142,098
Litigation settlement		9,000	37,821	11,856	
Net income	$ 23,251	$ 15,342	$ 10,909	$ 35,221	$ 91,768
Earnings per share:(A)					
Basic	$ 0.47	$ 0.29	$ 0.19	$ 0.57	$ 1.45
Diluted	$ 0.46	$ 0.29	$ 0.19	$ 0.55	$ 1.35
Shares used for earnings per share:(A)					
Basic	49,471	53,096	56,660	61,431	63,474
Diluted	50,937	53,816	58,081	63,778	68,119
Balance Sheet Data:					
Cash, cash equiv., and short-term investments	$ 86,076	$122,955	$123,807	$229,453	$258,359
Working capital	103,813	138,351	159,935	245,662	303,546
Total assets	163,963	200,592	219,925	321,507	362,721
Retained earnings	181,918	158,667	143,325	132,416	97,195
Stockholders equity	$125,799	$155,190	$176,278	$268,772	$316,793

EITF No. 00-25, Vendor Income Statement Characterization of Consideration Paid to a Reseller of the Vendor s Products (EITF 00-25) and EITF No. 01-09, Accounting for Consideration Given by a Vendor to a Customer or Reseller of the Vendor s Products (EITF 01-09), were adopted by VISX on January 1, 2002. The 2001, 2000, and 1999 information presented in the table above reflects the effects of this adoption as more fully described in Note 1 to the consolidated financial statements.

(A) All share and per share amounts have been adjusted to give effect for the 2 for 1 stock splits effected as 100% stock dividends in January and May 1999.

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

Forward Looking Statements

This Report contains forward-looking statements, including but not limited to our belief that: our CustomVue procedure represents a new standard in laser vision; correction;ongoing technical advances (including our CustomVue procedure) have the potential to improve a person s vision beyond that which can be obtained with contact lenses or glasses and may reduce concerns perceived by some consumers; acceleration of the market s acceptance of, and conversion to, our CustomVue procedure, or our ability to maintain or gain market share, or an increase in our penetration of the laser vision correction market in general, could cause a significant increase in our licensing revenue; there will not be a near-term change in our level of capital expenditures; an increase in the number of our FDA-approved indications will increase the pool of laser vision correction candidates and lead to increased procedure growth and licensing revenue; improvements in the United States economy will lead to increased consumer confidence, continued conversion to our CustomVue procedure, maintenance of our United States market share, increases in our revenue and earnings per share, and renewed support for the United States laser vision correction market in general; our selling, general and administrative expenses will increase between 5% and 9% in 2004; we will continue to generate cash from operations;

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procedure volume and conversion to CustomVue procedures from standard procedures will increase in 2004; there will be no significant growth in laser system revenues in 2004, and fewer WaveScan Systems will be sold in 2004 than in 2003; in 2004 our gross profit margin on license and other revenues will be similar to 2002 and 2003 levels; our gross profit margin on system revenues for 2004 will remain low; our research and development and regulatory expenses will increase slightly in 2004; and our cash flow from operations combined with our existing cash, cash equivalents and short-term investments will be sufficient to meet our needs during the coming twelve months. Forward-looking statements are estimates reflecting the best judgment of our senior management, and they involve a number of risks and uncertainties that could cause actual results to differ materially from those suggested by the forward-looking statements. Please see the section of this report entitled Risk Factors for a more thorough description of the risks that our business faces. Moreover, we caution you not to place undue reliance on these forward-looking statements, which speak only as of the date they were made. We do not undertake any obligation to publicly release any revisions to forward-looking statements to reflect events or circumstances after the date of this report or to reflect the occurrence of unanticipated events.

Overview

VISX, a Delaware corporation organized in 1988, is a worldwide leader in the design and development of proprietary technologies and systems for laser vision correction. Our primary operations are in Santa Clara, CA.

Our products require FDA approval in the United States and comparable regulatory agency approvals in other countries. Our approvals in the United States and key markets worldwide for laser vision correction cover most types of refractive vision disorders including:

- Nearsightedness;
- Farsightedness; and
- Astigmatism.

In certain key international markets, our CustomVue procedure is also approved for all of these refractive vision disorders. In May 2003, we obtained FDA approval for our new CustomVue procedure for nearsightedness and astigmatism.

We sell products worldwide and generate the majority of our revenues and cash through licensing fees charged for the performance of laser vision correction procedures using the VISX STAR System. The license fee charged for a particular procedure depends on whether the procedure is performed in the United States or internationally, and the type of procedure involved. In the United States, we have always charged a license fee for our standard procedure and charge a license fee for our CustomVue procedure that is more than twice the amount charged for our standard procedure. Additionally, we charge a standard price of $10 per procedure for the treatment cards. Internationally, for standard procedures we only charge a small fee per procedure for the treatment card. For CustomVue procedures we charge a significantly larger fee per procedure.

We believe our CustomVue procedure, which requires use of a VISX WaveScan System, represents a new standard in laser vision correction. It enables doctors to identify, measure, and correct imperfections in a patient s eye much more precisely than ever before, thus creating the potential for patients to experience better vision than is possible with glasses or contact lenses.

We believe we have the largest installed base of laser vision correction systems, with over 1300 systems in place worldwide. We also believe we maintained at least 60% share for procedures performed in the United States in 2003. According to MarketScope, we have held at least 60% market share since 1997.

Licensing revenues for procedures comprise the majority of our revenue and profit, and are predominantly derived from license fees from our United States customers. This has been especially true in recent years as the laser vision correction market has matured and the demand for new hardware systems and upgrades to those systems has declined. Licensing revenues grew 20% in 2003 compared with 2002 and generated approximately 96% gross margin on the sale of procedures. We evaluate this aspect of our business by tracking the following:

- The number of procedures sold;

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Trends in procedures sales, including conversion rates from standard to CustomVue procedures;

Market share for VISX and its competitors; and

Penetration of the overall laser vision correction market.

Any increase in license fee revenue that results from either an increase in the amount charged for a particular procedure or from an increase in overall procedure volume directly impacts our net income. As a result, our management team is focused on activities that will (i) accelerate the market s acceptance of, and conversion to, our CustomVue procedure; (ii) enable VISX to maintain or gain market share; and (iii) increase the penetration of the laser vision correction market in general. Progress on any one of these fronts offers the potential for growth in our licensing revenue.

We manage our expenses closely and plan to generate cash from our ongoing business operations in 2004. Historically, our primary non-operating use of cash has been to repurchase shares of our stock. We bought 3.5 million shares of stock in 2003 and intend to repurchase additional shares in 2004. Cash flow permitting, we will also continue to investigate areas where we can expand our presence in the refractive surgery market. This could result in using cash for the acquisition of technology or a company. Our capital expenditures have been in the range of $1.4 million to $4 million per year in the past five years. We do not expect a near-term change in this level of expenditures. We have no long term debt.

Looking to 2004, our business is highly leveraged on procedure volume, and increasingly, the conversion to CustomVue procedures. A number of factors, the most material of which are set forth below, could impact our success in 2004 and beyond:

Market acceptance of laser vision correction. Increased acceptance of laser vision correction by both doctors and patients in the United States and key international markets is essential for our continued growth. Laser vision correction has penetrated less than 6% of the eligible United States population, and our profitability and continued growth will be largely dependent on increasing levels of market acceptance and procedure growth, especially with regard to our higher-priced CustomVue procedure. We expect that ongoing technical advances, such as the CustomVue procedure, will enhance the quality of patients vision which may also increase consumer confidence in laser vision correction surgery.

Our ability to expand the refractive vision disorder range approved by the FDA for treatment with the VISX STAR System. We continue to expand the list of FDA-approved refractive vision disorder range that can be treated with VISX STAR Systems. As the number of FDA-approved indications increases, so does the pool of eligible laser vision correction candidates and the potential for increased procedure growth and licensing revenue.

Our competition. Competition in the laser vision correction market is intense. Many of our competitors have greater resources and a stronger international market presence. As a result, we compete aggressively to obtain this business and experience low gross margins on the sale of equipment.

The United States economy. Because we have always charged a license fee for procedures sold in the United States, the United States remains, by far, our most significant market for licensing revenue. Economic conditions in the United States therefore impact our licensing revenue more than global economic conditions. Industry experts have tracked procedure volume in the United States against economic indicators such as consumer confidence. They have noted a correlation between consumer confidence and the number of laser vision correction procedures performed per quarter. We believe that a rebound in the United States economy and increases in consumer confidence could provide renewed support for the laser vision correction market in the United States. Alternatively, a decline in economic conditions in the United States could result in a decline in the number of laser vision correction procedures performed.

We believe that our revenue and profit will improve in 2004 as a result of various factors including continued conversion to the CustomVue procedure maintenance, at least, of our United States market share and improvements in the United States economy. We plan for an increase in operating expenses of 5% to 9% with a goal of increasing our operating margins to greater than 30% of sales. We expect to continue to generate cash from operations.

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Results of Operations

The following table sets forth, for the periods indicated, certain financial information as a percentage of total revenue:

	Year Ended December 31,		
	2003	2002	2001
Revenues:			
License and other revenues	61%	52%	52%
System revenues	26	35	34
Service and parts revenues	13	13	14
Total revenues	100	100	100
Costs and Expenses:			
Cost of license and other revenues	2	2	3
Cost of system revenues	25	24	24
Cost of service and parts revenues	9	10	8
Selling, general and administrative	27	31	26
Research, development and regulatory	13	13	12
Total costs and expenses	76	80	73
Income From Operations	24	20	27
Other Income (Expense):			
Interest income	2	4	7
Litigation settlement		(6)	(23)
Other income (expense), net	2	(2)	(16)
Income Before Provision For Income Taxes	26	18	11
Provision for income taxes	10	7	4
Net Income	16%	11%	7%

2003 Compared to 2002

	Year Ended December 31,		
	2003	2002	Change
		(000 s)	
License and other revenues	$ 87,351	$ 72,524	20%
Percent of revenues	60.7%	51.8%	
System revenues	$ 38,248	$ 48,595	(21)%
Percent of revenues	26.6%	34.7%	
Service and parts revenues	$ 18,306	$ 18,807	(3)%
Percent of revenues	12.7%	13.5%	
Total	$143,905	$139,926	3%

License and Other Revenues

License and other revenues grew 20%, or $14.8 million, in 2003 compared with 2002, reflecting primarily the conversion to our new CustomVue procedure by our United States customers. We introduced the CustomVue procedure in June in the United States and have sold the product for more than double the price of our standard procedure. In the United States, CustomVue procedures represented 24% of the procedure orders in the third quarter and 29% of the procedure volume in the fourth quarter. In the United States for the full year, 15% of our procedure orders were CustomVue procedures.

Our total United States procedure volume for the year grew by 3% over the prior year and also contributed modestly to the increase in license and other revenue. As the economy improved in the second half of 2003, the procedure growth

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was more significant. It grew 17% in the second half of 2003 compared with the second half of 2002. We believe this increase represents the direct impact of favorable economic conditions on interest in laser vision correction surgery.

Based on economists projections for a more favorable economic environment in 2004 and our belief that customers will continue to adopt our CustomVue product, we believe that our procedure volume and conversion levels to CustomVue procedures from standard procedures will increase in 2004. We cannot be certain of this projection since there is uncertainty in the economic outlook and the decision to have laser vision correction surgery is influenced by many factors. The procedure is elective and generally not covered by medical insurance; therefore it competes with many types of purchases for consumers discretionary spending. Perceptions about safety and effectiveness of the procedure are additional considerations. The lack of long-term follow-up studies of the procedure combined with media coverage of selected unfavorable outcomes may contribute to uncertainty and delay by some potential consumers. As such, we cannot accurately predict when, or to what extent, these anticipated changes in the economy and technology will impact our license and other revenues.

System Revenues

System revenues comprise sales and leases of the following equipment:

- VISX STAR System;
- Upgrades to the VISX STAR System; and
- WaveScan Systems.

System revenues were negatively impacted by:

- Less upgrade revenue, which resulted because 80% of our United States customers had already upgraded their VISX STAR S2™ to the STAR S3® System by the end of 2002;
- Fewer VISX STAR System sales due to the continued weak economic environment, competitive pricing pressures for excimer lasers, and in Asia Pacific, political tensions in Korea and the outbreak of SARS in 2003.

This was offset by the increase in sales of WaveScan Systems which:

- Increased to 440 units compared with 202 units in the prior year;
- Enables over 80% of our United States customers to perform CustomVue procedures that generate higher revenue and profit per procedure.

The market for laser systems remains competitive. We experienced lower per unit pricing on laser sales in 2003 compared with 2002. We believe that we have maintained our system market share in the United States and in our key international markets. MarketScope estimates that VISX is the leader in the worldwide market with approximately 30% of worldwide laser placements.

In 2004, we believe there will be no significant growth in revenues from laser system revenues and that the sale of WaveScan systems will be less than in 2003, since most of our customers have already purchased a WaveScan system.

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Service and Parts Revenues

Service and parts revenues in 2003 were $0.5 million lower than in 2002. This was primarily the result of a new service plan which effectively reduces the price charged for service contracts on laser systems with lower than average procedure volume.

	Year Ended December 31,		
	2003	2002	Change
		(000 s)	
Cost of license and other revenues	$ 3,507	$ 3,302	6%
Percent of related revenues	4.0%	4.6%	
Cost of system revenues	$35,328	$33,064	7%
Percent of related revenues	92.4%	68.0%	
Cost of service and parts revenues	$13,235	$14,439	(8)%
Percent of related revenues	72.3%	76.8%	
Selling, general and administrative	$38,583	$42,537	(9)%
Percent of total revenues	26.8%	30.4%	
Research, development and regulatory	$18,647	$18,714	(0)%
Percent of total revenues	13.0%	13.4%	

Cost of License and Other Revenues

Cost of license and other revenues increased slightly in 2003 compared with 2002. The increase was due to slightly higher procedure sales that resulted in additional licensing support in 2003. We experienced a gross profit margin on license and other revenues of approximately 96% in 2003 and 95% in 2002. We anticipate similar margins for this product in 2004.

Cost of System Revenues

Cost of system revenues increased $2.3 million, due to the increase in WaveScan system sales. This was partially offset by fewer VISX STAR System sales and fewer sales of upgrades.

Our gross profit margin on system revenues declined in 2003 from 2002 because we sold fewer system upgrades and we earned less revenue on average per unit sold. We believe that our gross profit margin on system revenues for 2004 will remain low.

Cost of Service and Parts Revenues

Cost of service and parts revenues decreased approximately $1.2 million for the year ended December 31, 2003 compared with the year ended December 31, 2002. The decrease was due to fewer requirements for service on a larger installed base of stable products in the United States.

Selling, General, and Administrative Expenses

Selling, general, and administrative expenses declined by approximately $4.0 million to $38.6 million in 2003 compared with 2002. The change reflects primarily the following items:

Legal expenses declined $7.6 million in 2003 from 2002. We settled a lawsuit against Nidek in the first quarter of 2003 which was the main reason for the $9.7 million reduction in gross legal expenses in 2003 compared with 2002. Offsetting gross legal expenses, we received insurance reimbursements of $5.3 million and $7.5 million in 2003 and 2002, respectively, related to legal expenses we incurred in connection with the Nidek lawsuits;

An increase in marketing and sales expenses of $4.9 million to promote CustomVue.

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In 2004, our current plan for operations includes:

A modest increase in marketing and sales expenses as we continue to promote our CustomVue procedure;

Administrative spending similar to 2003 levels, and

An increase in legal expenses, because such expenses will not be offset by insurance reimbursement in 2004.

We believe these factors will result in an increase of 5% to 9% in our selling, general and administrative expenses.

Research and Development and Regulatory Expenses

Our research and development and regulatory expenses in 2003 remained similar to 2002 levels. We focused our efforts on next generation technologies and developments for laser vision correction, including:

Laser platforms such as our STAR S4^{tm} laser system;

Eye diagnostic units such as our WaveScan System;

New methods for correcting vision disorders including further indications (such as hyperopia and high myopia) for our CustomVue treatment;

Continued research and clinical trials for treatment of presbyopia; and

Continued funding of early stage research at Stanford University for future treatments for age-related macular degeneration.

In 2004, we anticipate that our research and development and regulatory expenses will increase slightly compared to our expenditures in 2003.

Interest and Other Income

Interest income declined in 2003 from 2002 as a result of:

Lower average cash balances due to use of cash for the repurchase of our stock and payment of the Nidek settlement; and

Lower average yields on our portfolio of cash and investments compared to 2002 due to market declines in interest rates.

Income Tax Provision

Our effective tax rate increased in 2003 from 2002 due principally to lower research and development tax credits.

Results of Operations

2002 Compared to 2001

	Year Ended December 31,		
	2002	**2001**	**Change**
		(000 s)	
License and other revenues	$ 72,524	$ 86,616	(16)%
Percent of revenues	51.8%	52.5%	
System revenues	$ 48,595	$ 55,592	(13)%
Percent of revenues	34.7%	33.7%	
Service and parts revenues	$ 18,807	$ 22,808	(18)%
Percent of revenues	13.5%	13.8%	

Total	$139,926	$165,016	(15)%

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License and Other Revenues

License and other revenue in 2002 was $14.1 million lower than in 2001 mainly due to a decline in the volume of US procedures for which VISX earned procedure fees. We believe the economic recession was the principal cause of the decline in our procedure volume and the United States laser vision correction market as a whole in 2002 from 2001.

System Revenues

System revenues in 2002 were $7.0 million lower than in 2001 due to a decline in sales of VISX STAR Systems and VISX STAR System upgrade revenue, which was partially offset by an increase in the sale of WaveScan Systems.

System revenues were negatively impacted by:

VISX STAR System revenues revenue declined $7.4 million (from $33.8 to $26.4 million) due to the recession (both United States and worldwide) and aggressive pricing tactics by competitors; and

Laser upgrade revenue decreased $8.0 million (from $19.6 to $11.6 million) because a majority of our US customers upgraded their VISX STAR S2 Systems to the new VISX STAR S3® model during 2001. Since we began installing the VISX STAR S3 upgrade in the fourth quarter of 2000, we had upgraded approximately 80% of the VISX STAR S2 lasers based in the United States by the end of 2002.

This was offset by the increase in sales of WaveScan Systems which:

Increased $8.5 million (from $2.1 to $10.6 million) as we continued to extend our rollout of this product.

Service and Parts Revenues

Service and parts revenues in 2002 were $4.0 million lower than in 2001 mainly due to a new service plan which effectively reduced the price charged for service contracts on laser systems with lower than average procedure volume.

	Year Ended December 31,		
	2002	2001	Change
		(000 s)	
Cost of license and other revenues	$ 3,302	$ 5,554	(41)%
Percent of related revenues	4.6%	6.4%	
Cost of system revenues	$33,064	$40,248	(18)%
Percent of related revenues	68.0%	72.4%	
Cost of service and parts revenues	$14,439	$12,638	14%
Percent of related revenues	76.8%	55.4%	
Selling, general and administrative	$42,537	$41,946	1%
Percent of revenues	30.4%	25.4%	
Research, development and regulatory	$18,714	$19,458	(4)%
Percent of revenues	13.4%	11.8%	

Cost of License and Other Revenues

Cost of license and other revenues declined $2.3 million in 2002 compared with 2001. The decrease was due to lower procedure volume in 2002, as well as additional licensee support provided in 2001 compared to 2002.

Cost of System Revenues

Cost of system revenues declined $7.2 million, which was due primarily to lower cost of revenues resulting from lower sales of laser upgrades. This was partially offset by higher cost of VISX STAR System and WaveScan System revenue, based on increased WaveScan System sales in 2002 compared with 2001.

Cost of Service and Parts Revenues

Cost of service and parts revenues increased $1.8 million to $14.4 million in 2002 from $12.6 million in 2001. The increase was due to higher costs to service a larger installed base of systems.

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Selling, General, and Administrative Expenses

Selling, general, and administrative expenses increased $0.6 million in 2002 compared with 2001. The net increase was due to;

a $1.5 million increase in selling and marketing expenses primarily related to additional marketing research: and

a $1.2 million increase attributable to an impairment charge related to our investment in Medjet Inc.

These increases were partially offset by;

a $1.3 million reduction in provision for doubtful accounts receivables in 2002 over 2001. Our policy is to provide allowances against receivables based on our assessment of our customers ability to meet their financial obligations. As a result of this analysis, our provision for doubtful accounts receivable was $1.4 million in 2002 as compared to $2.7 million in 2001; and

a decrease in legal expenses in 2002.

Research and Development and Regulatory Expenses

Our research and development and regulatory expenses decreased $0.7 million. We continued to focus on next generation technologies and developments for laser vision correction. These included laser platforms such as our STAR S4 laser system, eye diagnostic units such as our WaveScan System, and new methods for correcting vision disorders including our CustomVue treatment and early research and clinical trials on treatments for presbyopia. We also continued funding early stage research at Stanford University for future treatments for age-related macular degeneration.

Interest and Other Income

Our average balance of cash invested in interest bearing securities was lower in 2002 than in 2001 due to cash used to repurchase our stock. Additionally, as market interest rates decreased throughout the year the average yield on our portfolio of cash and investments was lower in 2002 compared to 2001. Accordingly, interest income declined in 2002 from 2001.

Income Tax Provision

Our effective tax rate decreased in 2002 from 2001 due higher tax benefits associated with our sales outside the United States and research and development.

Quarterly Results of Operations

In the following table we present selected items from our recent quarterly financial results (in 000 s except earnings per share).

	2003				2002			
	1st Qtr	2nd Qtr	3rd Qtr	4th Qtr	1st Qtr	2nd Qtr	3rd Qtr	4th Qtr
Total revenues	$34,433	$31,986	$39,268	$38,218	$36,585	$36,639	$30,560	$36,142
Cost of revenues	12,824	11,390	16,335	11,521	12,365	11,559	11,539	15,342
Total costs and expenses	26,324	27,033	31,687	24,256	27,367	28,425	24,971	31,293
Income from operations	8,109	4,953	7,581	13,962	9,218	8,214	5,589	4,849
Litigation settlement								9,000
Income (loss) before provision (benefit) for income taxes	9,052	6,771	7,950	14,284	10,749	9,775	7,094	(3,137)
Provision (benefit) for income taxes	3,576	2,673	3,085	5,472	4,246	3,859	2,625	(1,591)
Net income (loss)	$ 5,476	$ 4,098	$ 4,865	$ 8,812	$ 6,503	$ 5,916	$ 4,469	$ (1,546)

Earnings (loss) per share, diluted	$ 0.11	$ 0.08	$ 0.10	$ 0.17	$ 0.12	$ 0.11	$ 0.08	$ (0.03)
Shares used for earnings (loss) per share, diluted	51,805	51,406	50,132	50,716	55,581	54,809	52,904	51,541

Seasonal Variation. Typically we experience an increase in procedure-related revenue in the United States market in the first quarter of each calendar year. We attribute this increase to consumers using the annual renewal of funding under the Internal Revenue Service Code section 125 pre-tax medical savings plan to purchase laser vision correction for

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themselves. Laser vision correction is not generally covered by medical insurance. Our equipment and procedure revenues tend to decline in the summer.

Critical Accounting Policies, Estimates and Judgments

We follow accounting principles generally accepted in the United States (GAAP) in preparing our financial statements. As part of this work, we must make many estimates and judgments about future events. These affect the value of the assets and liabilities, contingent assets and liabilities, and revenues and expenses reported in our financial statements. We believe these estimates and judgments are reasonable and we make them in accordance with our accounting policies based on information available at the time. However, actual results could differ from our estimates and could require us to record adjustments to expenses or revenues material to our financial position and results of operations in future periods. We believe our most critical accounting policies, estimates and judgments include the following:

Revenue Recognition

Our revenue recognition policy is described in note 1 to the Financial Statements.

We are also required to ensure that collectibility is reasonably assured before we recognize revenue. Accordingly, we evaluate our customers for credit worthiness and only recognize revenue if we believe that we have reasonable assurance that amounts will be collected. Where we are unable to assess with reasonable assurance that amounts will be collected, we defer revenue recognition until the payments are received. This is occasionally the case with customers who have recently set themselves up in business and typically where the customer is thinly capitalized.

Accounts Receivable

At the end of each accounting period, we estimate the reserve necessary for accounts receivable that will ultimately not be collected from customers. To develop this estimate, we review all receivables and identify those accounts with problems. For these problem accounts, we estimate individual, specific reserves based on our analysis of the payment history, operations and finances of each account. For all other accounts, we review historical bad debt trends, general and industry specific economic trends, customer concentrations, and current payment patterns to estimate the reserve necessary to provide for payment defaults that cannot be specifically identified but can be expected with reasonable probability to occur in the future. We face two particular challenges in estimating these reserves: concentration of credit with certain large customers and the potential for significant change in the overall health of the national economies in the markets we serve. Unexpected deterioration in the health of either a large customer or a national economy could lead to a material adverse impact on the collectibility of our accounts receivable and our future operating results. Our allowance for doubtful accounts at December 31, 2003, 2002 and 2001, as a percentage of gross accounts receivable was 13.3%, 9.4% and 12.3% respectively. At December 31, 2003, a one-percentage point deviation in our allowance for doubtful accounts as a percentage of accounts receivable would have resulted in an increase or decrease in expense of approximately $0.3 million.

Inventories

Adjustments to the carrying value of inventory for excess and obsolete items are based, in part, on our estimate of demand over the following 6 months. This estimate, though based on our historical experience and consideration of other relevant factors, (such as the current economic climate), is subject to some uncertainty. Amounts charged to income for excess and obsolete inventory for the years ending December 31, 2003, 2002 and 2001 as a percentage of total revenues in 2003, 2002 and 2001, were all less than 0.5%. To date, our estimates have been materially accurate and subject to any major changes in our business model, our operating environment or the economy, and taking consideration of the ongoing development of our technology, we do not expect either our methodology or the accuracy of our estimates to change significantly in the future.

Legal Contingencies

At the end of each accounting period, we review all outstanding legal matters. If we believe it is probable that we will incur a loss as a result of the resolution of a legal matter and we can reasonably estimate the amount of the loss, we accrue our best estimate of the potential loss. It is very difficult to predict the future results of complex legal matters, although historically, the amounts we have paid out have been materially similar to the amounts that we have accrued. New developments in legal matters can cause changes in previous estimates and result in significant changes in loss

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accruals. Currently we are not aware of any pending or threatened legal actions against us that we believe could materially adversely affect our business, financial condition or results of operations. However, we could in the future be subject to litigation claims that could cause us to incur significant expenses and put our business, financial position, and results of operations at material risk.

Liquidity and Capital Resources

Cash, cash equivalents and short-term investments and working capital were as follows:

	2003	Change	2002	Change	2001
Cash, cash equivalents, and short-term investments	$ 86,076	(30)%	$122,955	(1)%	$123,807
Working capital	103,813	(25)%	138,351	(13)%	159,935
Stockholders equity	125,799	(19)%	155,190	(12)%	176,278

Our cash, cash equivalents, and short-term investments consist principally of money market funds, and bonds issued by the United States government, government sponsored enterprises and corporations. All of our short-term investments are classified as available-for-sale under the provisions of Statement of Financial Accounting Standards No. 115, Accounting for Certain Investments in Debt and Equity Securities. The securities are carried at fair market value with the unrealized gains and losses, net of tax, included in accumulated other comprehensive income, which is reflected as a separate component of stockholders equity. Gains and losses are recognized when realized on the consolidated statements of operations.

Cash, cash equivalents, and short-term investments were $86.1 million at December 31, 2003, a decline of $36.9 million compared with December 31, 2002. It was impacted principally by:

Stock repurchases of $63.0 million;

Positive cash flow from operating activities of $26.8 million; and

Proceeds from issuance of common stock related to employee participation in employee stock programs generating $8.2 million.

Operating activities generated $26.8 million in cash in 2003 compared with $40.2 million provided in 2002. In 2003 we:

Generated $37.4 million of cash from net income plus non-cash related expenses ($14.2 million);

Used cash to pay $9.0 million included in accrued liabilities as of December 31, 2002 to Nidek for settlement of antitrust and related claims;

Increased accounts receivables balances due primarily to higher sales levels in the latter half of the year; and

Engaged in a higher number of operating lease arrangements with our physicians whereby we retain ownership of the system and receive revenue for the system generally over several years on a per procedure program. As such, we hold these leased systems in property, plant and equipment and amortize them to cost of system revenues over the term of the lease. New placements of equipment under these types of leases negatively impacted our cash by approximately $8.1 million in 2003; and.

Utilized prepaid taxes and deferred tax assets to reduce income tax payments otherwise due during 2003 by $6.4 million.

Net cash provided by investing activities was $15.2 million in 2003, down from $19.9 million provided in 2002. The principal movements in cash provided by investing activities were due to the investment in, and maturity of short-term investments. This was partially offset in 2003 by a payment of $5.9 million for acquired patents and technology assets from 20/10 Perfect Vision Optische Gerate GmbH. Capital expenditure decreased by $1.2 million to $1.4 million.

Cash used in financing activities was $54.8 million in 2003, up from $37.8 million used in 2002. The principal factor that contributed to the cash used in financing activities was the cash used to repurchase 3.5 million shares and 3.9 million shares of VISX stock on the open market in 2003 and 2002, respectively. This was partially offset by cash received upon the issuance of stock under employee stock programs of $8.2 million and $4.9 million in 2003 and 2002, respectively.

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On April 4, 2001, our Board of Directors authorized a Stock Repurchase Program under which up to 10 million shares of VISX common stock may be repurchased. In accordance with this authorization and applicable securities laws, we have repurchased 7.0 million shares on the open market cumulatively through December 31, 2003, at a total cost of $90.4 million. Accordingly, 3.0 million shares remain available as of December 31, 2003 for repurchase under the Board of Directors April 2001 authorization. On May 28, 2003, the Board of Directors authorized the repurchase of an additional 3.5 million shares of VISX stock at a total cost of $63.0 million, all of which were purchased during the quarter ended June 30, 2003. Before repurchasing shares we consider a number of factors including market conditions, the market price of the stock, and the number of shares needed for employee benefit plans. As a result, we cannot predict the number of shares that we may repurchase in the future. Purchases of short-term investments represent reinvestment into short-term investments of the proceeds from short-term investments that matured and investment of cash and cash equivalents. As of December 31, 2003, we did not have any borrowings outstanding, nor any credit agreements.

Our normal credit terms granted to customers are net 30 to 60 days. In an effort to promote the growth of the laser vision correction industry and the use of VISX STAR Systems and WaveScan Systems, we provide long-term financing to customers for their purchase of our equipment in certain markets. We consider a number of factors including industry practice, competition, and our evaluation of customers credit worthiness in determining when to offer such financing.

We believe our operations will generate cash in 2004 at a level equal to or greater than in 2003. We believe this will exceed cash required to fund our working capital and capital equipment needs during the coming twelve months. In addition, we have $86.1 million in cash, cash equivalents, and short-term investments as of December 31, 2003 to provide for unforeseen contingencies and to support strategic objectives including the development or acquisition of new technologies and our Stock Repurchase Program.

In May 2002, we entered into an exclusive worldwide license agreement for a portfolio of patents held by Luis Ruiz, MD, relating to the treatment of presbyopia with multifocal ablations. VISX also signed an agreement with Tracey Technologies, LLC for rights to Tracey s ray tracing technology for use in customized laser vision correction treatments. If clinical and regulatory milestones specified in both agreements are achieved, VISX will be committed to make additional payments of approximately $2.0 million in connection with these two agreements. VISX could be obligated for royalties in the future based on any future sales of the associated products.

The impact that our contractual obligations as of December 31, 2003 are expected to have on our liquidity and cash flow in future periods is as follows (in thousands):

	Payments Due by Period				
	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years
Contractual Obligations					
Operating Lease Obligations	$ 8,788	$2,079	$5,893	$816	
Purchase Obligations	5,559	5,491	68		
Total	$14,347	$7,570	$5,961	$816	$

New Accounting Pronouncements

In July 2002, the FASB issued Statement No. 146, Accounting for Costs Associated with Exit or Disposal Activities (SFAS 146) and nullified EITF Issue No. 94-3 Liability Recognition for Certain Employee Termination Benefits and Other Costs to Exit an Activity (including Certain Costs Incurred in a Restructuring . SFAS 146 requires that a liability for a cost associated with an exit or disposal activity be recognized when the liability is incurred, whereas EITF No. 94-3 had recognized the liability at the commitment date to an exit plan. We are required to adopt the provisions of SFAS 146 effective for exit or disposal activities initiated after December 31, 2002. The adoption of SFAS 146 did not have a material impact on our financial position or results of operations.

In November 2002, the EITF reached a consensus on Issue No. 00-21, Revenue Arrangements with Multiple Deliverables. EITF Issue No. 00-21 provides guidance on how to account for arrangements that involve the delivery or performance of multiple products, services and/or rights to use assets. The provisions of EITF Issue No. 00-21 apply to revenue arrangements entered into in fiscal periods beginning after June 15, 2003. The adoption of EITF Issue No. 00-21 did not have a material impact on our financial position or results of operations.

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In December 2003, the FASB revised Interpretation No. 46 (FIN 46), Consolidation of Variable Interest Entities, an Interpretation of ARB No. 51 which it had originally issued in January 2003. As revised, FIN 46 requires certain variable interest entities to be consolidated by the primary beneficiary of the entity if the equity investors in the entity do not have the characteristics of a controlling financial interest or do not have sufficient equity at risk for the entity to finance its activities without additional subordinated financial support from other parties. As revised, application of FIN 46 is required for interests in variable interest entities or potential variable interest entities (commonly referred to as special-purpose entities) for periods ending after December 15, 2003. Application for all other types of entities covered by FIN 46 is required in financial statements for periods ending after March 15, 2004. The adoption of FIN 46 as revised, did not have a material impact on our financial position or results of operations.

In May 2003, the FASB issued Statement of Financial Accounting Standards No. 150 (SFAS 150), Accounting for Certain Financial Instruments with Characteristics of Both Liabilities and Equity . SFAS 150 requires that certain financial instruments, which under previous guidance were accounted for as equity, must now be accounted for as liabilities. The financial instruments affected include mandatory redeemable stock, certain financial instruments that require or may require the issuer to buy back some of its shares in exchange for cash or other assets and certain obligations that can be settled with shares of stock. SFAS 150 is effective for all financial instruments entered into or modified after May 31, 2003, and otherwise is effective at the beginning of the first interim period beginning after June 15, 2003, although certain aspects have been delayed pending further clarifications. We do not expect the adoption of SFAS 150 to have a material impact on our financial position or results of operations.

In December 2003, the SEC issued Staff Accounting Bulletin (SAB) No. 104 Revenue Recognition which codifies, revises and rescinds certain sections of SAB No. 101, Revenue Recognition , in order to make this interpretive guidance consistent with current authoritative accounting and auditing guidance and SEC rules and regulations. The changes noted in SAB No. 104 did not have a material effect on our financial position or results of operations.

Risk Factors

This report contains forward-looking statements that involve risk and uncertainty. The factors set forth below, which are not the only risks we face, may cause our actual results to vary from those contemplated by forward-looking statements set forth in this report and should be considered carefully in addition to the other information presented in this report. If any of the following risks actually occur, our business, results of operations or cash flows could be adversely affected. Our results of operations have varied widely in the past and could continue to vary significantly. In addition, our actual results may differ significantly from the results contemplated by the forward-looking statements. Accordingly, we believe that our results of operations in any given period may not be a good indicator of our future performance.

Market Acceptance. Our business depends upon broad market acceptance of laser vision correction by both doctors and patients in the United States and key international markets. Laser vision correction has penetrated less than 6% of the eligible United States population, and our profitability and continued growth will be largely dependent on increasing levels of market acceptance and procedure growth, especially with regard to our higher-priced CustomVue procedure. Although laser vision correction offers a more predictable outcome and more precise results than other surgical methods used to correct refractive disorders, it is not without risk. Potential complications and side effects include: post-operative discomfort, corneal haze (an increase in the light scattering properties of the cornea) during healing, glare/halos (undesirable visual sensations produced by bright lights), decreases in contrast sensitivity, temporary increases in intraocular pressure in reaction to procedure medication, modest fluctuations in refractive capabilities during healing, modest decrease in best corrected vision (i.e., with corrective eyewear), unintended over- or under-corrections, regression of effect, disorders of corneal healing, corneal scars, corneal ulcers, and induced astigmatism (which may result in blurred or double vision and/or shadow images). Some consumers may choose not to undergo laser vision correction because of these complications or more general concerns relating to its safety and efficacy or a resistance to surgery in general. Alternatively, some consumers may elect to delay undergoing laser vision correction surgery because they believe improved technology or methods of treatment will be available in the near future. Should either the ophthalmic community or the general population turn away from laser vision correction as an alternative to existing methods of treating refractive vision disorders, or if future technologies replaced laser vision correction, these developments could have a material adverse effect on our business, financial position and results of operations.

Unfavorable Side Effects. The possibility of long-term side effects and adverse publicity regarding laser correction surgery could seriously harm our business. Laser vision correction is a relatively new procedure. Consequently, there is

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no long-term follow-up data beyond ten years that might reveal additional complications or unknown side effects. Any future reported side effects, other adverse events or unfavorable publicity involving patient outcomes resulting from the use of laser vision correction systems manufactured by VISX or any participant in the laser vision correction market, may have a material adverse effect on our business, financial position, and results of operations.

Government Regulation. We are subject to extensive government regulation, which increases our costs and could prevent us from selling our products. Government regulation includes inspection of and controls over research and development, testing, manufacturing, safety and environmental controls, efficacy, labeling, advertising, promotion, pricing, record keeping, the sale and distribution of pharmaceutical products and samples and electronic records and electronic signatures. In the United States, we must obtain FDA approval or clearance for each medical device that we market. The FDA approval process is typically lengthy and expensive, and approval is never certain. Products distributed outside of the United States are also subject to government regulation, which may be equally or more demanding. Our new products could take a significantly longer time than we expect to gain regulatory approval and may never gain approval. If a regulatory authority delays approval of a potentially significant product, our market value and operating results may decline. Even if the FDA or another regulatory agency approves a product, the approval may limit the indicated uses for a product, may otherwise limit our ability to promote, sell and distribute a product or may require post-marketing studies. If we are unable to obtain regulatory approval of our products, we will not be able to market these products, which would result in a decrease in our sales. Currently, we are actively pursuing approval for a number of our products from regulatory authorities in a number of countries, including, among others, the United States, countries in the European Union and Japan. Continued growth in our sales and profits will depend, in part, on the timely and successful introduction and marketing of some or all of these products.

The clinical trials required to obtain regulatory approvals are complex and expensive and their outcomes are uncertain. We incur substantial expense for, and devote significant time to, clinical trials but cannot be certain that the trials will ever result in the commercial sale of a product. We may suffer significant setbacks in clinical trials, even after earlier clinical trials showed promising results. Any of our products may produce undesirable side effects that could cause us or regulatory authorities to interrupt, delay or halt clinical trials of a product candidate. We, the FDA, or another regulatory authority may suspend or terminate clinical trials at any time if they or we believe the trial participants face unacceptable health risks.

Noncompliance with applicable United States regulatory requirements can result in fines, injunctions, penalties, mandatory recalls or seizures, suspensions of production, denial or withdrawal of pre-marketing approvals, recommendations by the FDA against governmental contracts and criminal prosecution. The FDA also has authority to request repair, replacement, or the refund of the cost of any device we manufacture or distribute. Regulatory authorities outside of the United States may impose similar sanctions for noncompliance with applicable regulatory requirements.

New Technologies. If we fail to keep pace with advances in our industry or fail to develop new methods of vision correction, customers may not buy our products and our revenue may decline. We must be able to manufacture and effectively market those products and persuade a sufficient number of eye care professionals to use the new products as well as new methods of vision correction such as our CustomVue procedure, that we introduce. Sales of our existing products may decline rapidly if a new product is introduced by one of our competitors or if we announce a new product that, in either case, represents a substantial improvement over our existing products. A decrease in procedure volume may also occur if consumers elect to delay undergoing laser vision correction surgery because they believe improved technology or methods of treatment will be available in the near future.

New Products May Not Be Commercially Viable. While we devote significant resources to research and development, our research and development may not lead to new products that achieve commercial success. The research and development process is expensive, prolonged, and entails considerable uncertainty. Development of a new medical device, from discovery through testing and registration to initial product launch, typically takes between three and seven years. Each of these periods varies considerably from product to product and country to country. Because of the complexities and uncertainties associated with ophthalmic research and development, products we are currently developing may not complete the development process or obtain the regulatory approvals required to market such products successfully. The products currently in our development pipeline may not be approved by regulatory entities and may not be commercially successful, and our current and planned products could be surpassed by more effective or advanced products.

Competition. Intense competition in the laser vision correction industry could result in the loss of customers, an inability to attract new customers, or a decrease in prices for our products. The medical device and ophthalmic laser industries are subject to intense competition and technological change. Not only does laser vision correction compete with more

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traditional vision correction options such as eyeglasses and contact lenses, it also competes with other technologies and surgical techniques such as intraocular lenses, and surgery using different types of lasers. In addition, the market for laser vision correction systems has become increasingly competitive in recent years as a result of FDA approval of several laser systems. The VISX STAR System competes with products marketed or under development by other laser and medical equipment manufacturers, many of which have greater financial and other resources. Competitors may offer laser systems at a lower price, may price their laser systems as part of a bundle of products or services, may develop procedures that involve a lower per procedure cost, or may offer products perceived as preferable to the VISX STAR System. In addition, medical companies, academic and research institutions and others could develop new therapies, including new medical devices or surgical procedures, for the conditions targeted by VISX, which therapies could be more medically effective and less expensive than laser vision correction, and could potentially render laser vision correction obsolete. Any such developments could have a material adverse effect on our business, financial position and results of operations.

Procedure Market Share. MarketScope estimates that we are currently the leader in the United States procedures market with a market share of over 60%. Because of this position all of our competitors target us and our market share in order to grow their own revenues. We can give no assurance that we will be able to maintain or grow our existing market share and we may, in fact, be required to incur considerable expenditures in order to maintain that share. Should our procedure market share decline, it could have a material adverse effect on our business, financial position and results of operations as well as the market price of our common stock.

Economic Conditions. Because laser vision correction is not subject to reimbursement from third-party payors such as insurance companies or government programs, the cost of laser vision correction is typically borne by individuals directly. Accordingly, weak or uncertain economic conditions may cause individuals to be less willing to incur the procedure cost associated with laser vision correction as was evidenced by our decline in revenues from 2002 compared to 2001 and from 2001 compared to 2000. A decline in economic conditions especially in the United States, could result in a decline in the number of laservision correction procedures performed and could have a material adverse effect on our business, financial position, and results of operations.

Significant Customers. A significant portion of our revenues is derived from sales to TLC Vision (TLC). TLC and its operating subsidiaries accounted for 16%, 14% and 17% of our total revenues in 2003, 2002 and 2001, respectively. Additionally, TLC, accounted for 22%, 22%, and 31% of our total receivables at December 31, 2003, 2002 and 2001, respectively. Should we lose a significant customer or if anticipated sales to a significant customer do not materialize, our business, financial position and results of operations may suffer. In addition, should a significant customer become unable to pay balances owed, we would have to increase our charges for bad debt expense which could have a material adverse effect on our business, financial position and results of operations.

Patents and Intellectual Property Disputes. Our business is dependent on the enforceability and the validity of our United States and foreign patents. We own over 200 United States and foreign patents and have more than 200 patent applications pending. In the past, our patents have been challenged on several fronts and we have asserted our patents against competitors. Generally, these proceedings centered on whether infringement of the patents had occurred, and on the validity or enforceability of the patents. While all of these proceedings have now been resolved, we may assert our patents against competitors in the future. If our patents were found to be invalid or unenforceable (or in the event that parties against whom VISX asserted patent infringement were found not to be infringing our patents) in any future proceedings, our ability to collect license fees from the parties to the litigation or from other sellers or users of laser vision correction equipment in the United States could suffer and our revenues could decline. In addition, other companies own United States and foreign patents covering methods and apparatus for performing corneal surgery with ultraviolet lasers. If we were accused of infringing such competitors patents and found to have infringed such patents, we could be subject to significant monetary liability and enjoined from distributing our products. Any one of these results could harm our business.

Product Liability Claims. We have and may become subject to product liability claims. We could be liable for injuries or damage resulting from use of the VISX STAR System or WaveScan System. In addition, a claim that an injury resulted from a defect in any VISX product, even if successfully defended, could damage our reputation. Although we possess insurance customarily obtained by businesses of our type (including insurance against product liability risks associated with the testing, manufacturing, and marketing of our products), product liability claims in excess of our insurance coverage could have a material adverse effect on our business, financial position, and results of operations.

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International Operations. We face risks due to our reliance on sales in international markets. During 2003, 2002, and 2001, we derived approximately 17%, 23% and 16%, respectively, of our revenues from sales to customers outside the United States. Our international presence exposes us to risks including:

- the need for export licenses;
- unexpected regulatory requirements;
- tariffs and other potential trade barriers and restrictions;
- political, legal and economic instability in foreign markets;
- longer accounts receivable cycles;
- difficulties in managing operations across disparate geographic areas;
- foreign currency fluctuations;
- reduced or limited protection of our intellectual property rights in some countries; and
- dependence on local distributors.

If one or more of these risks materialize, our sales to international customers may decrease and our costs may increase, which could negatively impact our revenues and operating results.

Distributors. Internationally, we sell our products through distributors. If we fail to maintain our existing distribution channels or develop additional channels in the future, our ability to sell products internationally could be impaired and our business harmed.

Third Party Financing Entities. We have relationships with third party financing entities that purchase our products directly and subsequently lease and/or sell these products to our end-user customers, or provide financing directly to customers who purchase our products directly from us. Should any third party financing entity or entities fail or refuse to pay us in a timely manner or at all, it could negatively affect our cash flows and could have a material adverse effect on our business, financial position and results of operations. In fact, DVI, which provided equipment purchase financing to our customers, entered into Chapter 11 bankruptcy proceedings in August 2003, and as a result, we recorded bad debt expense to increase our reserve for doubtful accounts to cover the entire $2.3 million of accounts receivables then outstanding from DVI.

Fixed Short-Term Expenses. Because our expenses are relatively fixed in the short term, our earnings will decline if we do not meet our projected sales. Any shortfall in revenues below expectations would likely have an immediate impact on our earnings per share, which could adversely affect the market price of our common stock. Our operating expenses, which include sales and marketing, research and development, and general and administrative expenses, are based on our expectations of future revenues and are relatively fixed in the short term. Accordingly, if revenues fall below expectations, we will not be able to reduce our spending rapidly in response to such a shortfall.

Acquisitions of Businesses or Technology. We have acquired technology assets and may need to continue to do so to retain our competitive position within the marketplace. If we acquire businesses, new products or technologies in the future, we may be required to amortize significant amounts of identifiable intangible assets and we may record significant amounts of goodwill that will be subject to annual testing for impairment. If we consummate one or more significant future acquisitions in which the consideration consists of stock or other securities, our existing stockholders ownership could be significantly diluted. If we were to proceed with one or more significant future acquisitions in which the consideration included cash, we could be required to use a substantial portion of our available cash. Additionally, such an acquisition could have a substantial impact on our business, our financial position and our results of operations.

Taxes. We operate throughout the United States and, consequently, are subject to various federal, state and local taxes, including sales, income, payroll, unemployment, property, franchise, capital and use tax on our operations, payroll, assets and services. Although we believe we have adequate provisions and accruals in our financial statements for tax liabilities,

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we cannot predict the outcome of all past and future tax assessments. If any taxing authority determines we owe amounts for taxes greater than we expect, our earnings may be negatively affected.

Key Personnel. The success of our business depends on the efforts and abilities of our senior management and other key personnel. We do not have long term employment agreements with any of our key personnel. The loss of any of our executive officers or other key employees could result in significant disruption to our ongoing operations and hurt our business. Additionally, our inability to attract new senior executives and key personnel could significantly impact our business results.

Single Sources For Key Components. The manufacture of the VISX STAR System and WaveScan System is a complex operation involving numerous procedures. We depend on single and limited sources for several key components. If any of these suppliers were to cease providing components, we would be required to locate and contract with a substitute supplier. We could have difficulty identifying a substitute supplier in a timely manner or on commercially reasonable terms. If the production of our products, parts and services were interrupted or could not continue in a cost-effective or timely manner, our business, financial position, and results of operations, could be materially adversely affected.

Volatility of our Stock Price. The market price of our common stock has experienced fluctuations and is likely to fluctuate significantly in the future. Our stock price can fluctuate for a number of reasons, including:

announcements about us or our competitors;

results or settlements of litigation;

quarterly variations in operating results;

the introduction or abandonment of new technologies or products;

changes in product pricing policies by us or our competitors;

changes in earnings estimates by analysts or changes in accounting policies; and

economic changes and political uncertainties.

In addition, stock markets have experienced significant price and volume volatility in recent years. This volatility has had a substantial effect on the market prices of securities of many public companies for reasons frequently unrelated or disproportionate to the operating performance of the specific companies. In addition, the securities of many medical device companies, including VISX, have historically been subject to extensive price and volume fluctuations that may affect the market price of their common stock. If these broad market fluctuations continue, they may adversely affect the market price of our common stock.

Proprietary Information and Inventions Agreements. We protect our proprietary technology, in part, through proprietary information and inventions agreements with employees, consultants and other parties. These agreements with employees and consultants generally contain standard provisions requiring those individuals to assign to us, without additional consideration, inventions conceived or reduced to practice by them while employed or retained by us, subject to customary exceptions. If any of our employees, consultants or others breach these agreements our competitors may learn of our trade secrets.

Changes to the Accounting for Stock Options. The Financial Accounting Standards Board has indicated that possible rule changes requiring expensing of stock options may be adopted in the near future. Currently, we include such expenses 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 include stock option expense for employee options in our reported financial statements. If accounting standards are changed to require us to expense stock options, our reported earnings will decrease significantly and our stock price could decline.

Exercising of Stock Options. As of December 31, 2003, there were an aggregate of 6,009,000 shares of our common stock issuable upon exercise of outstanding vested stock options. If these stock options are exercised, the total number of our traded shares will increase and this could adversely impact our earnings per share.

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Antitakeover Provisions in Our Charter Documents. In 2000, we adopted a stockholder rights plan. The presence of this plan could make it more difficult for a third party to engage in a takeover attempt, even a takeover attempt in which the potential purchaser offers to pay a per share price greater than the current market price for our common stock. In addition, the presence of the plan could delay or impede the removal of incumbent directors. These provisions may also impact the amount of interest investors have in our business.

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

Interest Rate Risk. We invest our cash, beyond that needed for daily operations, in high quality debt securities. We seek primarily to preserve the value and liquidity of our capital, and secondarily to safely earn income from these investments. To accomplish these goals, we invest only in debt securities issued by (1) the United States Treasury and United States government agencies and corporations and (2) United States corporations that meet the following criteria:

Rated investment grade A or higher by the major rating services;

Can readily be resold for cash; and

Mature no more than 3 years from our date of purchase.

The following table shows the expected cash flows at maturity from our investments in debt securities ($000 s).

	2004	2005	2006	2007	2008	Beyond
Cash equivalents and short-term investments (amortized cost as of December 31, 2003)	$34,909	$35,265	$	$	$	$
Weighted average effective interest rate	1.47%	1.72%				

Foreign Currency Exchange Rate Risk. We sell products in various international markets. Virtually all of these sales are contracted and paid for in United States Dollars. As of December 31, 2003 we have no outstanding foreign currency hedge contracts. Accordingly, we have no material foreign currency exchange risk as of December 31, 2003.

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

VISX, INCORPORATED AND SUBSIDIARIES

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VISX, INCORPORATED AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

	December 31,	
	2003	2002
	(In thousands, except share and per share amounts)	
ASSETS		
Current Assets		
Cash and cash equivalents	$ 24,895	$ 37,687
Short-term investments	61,181	85,268
Accounts receivable, net of allowances for doubtful accounts of $4,195 and $2,563, respectively	27,432	24,559
Inventories	11,219	12,751
Deferred tax assets and prepaid expenses	17,250	23,488
Total current assets	141,977	183,753
Property and Equipment, net	9,306	6,498
Long-Term Deferred Tax and Other Assets	12,680	10,341
Total Assets	$ 163,963	$ 200,592
LIABILITIES AND STOCKHOLDERS EQUITY		
Current Liabilities		
Accounts payable	$ 3,442	$ 4,341
Accrued liabilities and other current liabilities	34,722	41,061
Total current liabilities	38,164	45,402
Commitments and Contingencies (Notes 9 and 12)		
Stockholders Equity:		
Common stock $.01 par value, 180,000,000 shares authorized; 64,990,089 shares issued at December 31, 2003 and 2002	650	650
Additional paid-in capital	201,108	202,700
Less: 16,295,297 and 13,652,256 common stock treasury shares at December 31, 2003 and 2002, respectively, at cost	(258,218)	(208,748)
Accumulated other comprehensive income	341	1,921
Retained earnings	181,918	158,667
Total stockholders equity	125,799	155,190
Total Liabilities and Stockholders Equity	$ 163,963	$ 200,592

See accompanying notes to consolidated financial statements.

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VISX, INCORPORATED AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF OPERATIONS

	Year Ended December 31,		
	2003	2002	2001
	(In thousands, except per share data)		
Revenues:			
License and other revenues	$ 87,351	$ 72,524	$ 86,616
System revenues	38,248	48,595	55,592
Service and parts revenues	18,306	18,807	22,808
Total revenues	143,905	139,926	165,016
Costs and Expenses:			
Cost of license and other revenues	3,507	3,302	5,554
Cost of system revenues	35,328	33,064	40,248
Cost of service and parts revenues	13,235	14,439	12,638
Selling, general and administrative	38,583	42,537	41,946
Research, development and regulatory	18,647	18,714	19,458
Total costs and expenses	109,300	112,056	119,844
Income From Operations	34,605	27,870	45,172
Other Income (Expense):			
Interest income	3,452	5,611	10,680
Litigation settlement		(9,000)	(37,821)
Other income (expense), net	3,452	(3,389)	(27,141)
Income Before Provision For Income Taxes	38,057	24,481	18,031
Provision for income taxes	14,806	9,139	7,122
Net Income	$ 23,251	$ 15,342	$ 10,909
Earnings Per Share			
Basic	$ 0.47	$ 0.29	$ 0.19
Diluted	$ 0.46	$ 0.29	$ 0.19
Shares Used For Earnings Per Share			
Basic	49,471	53,096	56,660
Diluted	50,937	53,816	58,081

See accompanying notes to consolidated financial statements.

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VISX, INCORPORATED AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY AND COMPREHENSIVE INCOME