STAAR SURGICAL CO
Form 10-K/A
April 21, 2005

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UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 10-K/A
Amendment No. 1

(Mark One)

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

For the fiscal year ended December 31, 2004

or

o **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the transition period from to

Commission file number: 0-11634

STAAR SURGICAL COMPANY
(Exact name of registrant as specified in its charter)

Delaware	**95-3797439**
(State or other jurisdiction of incorporation or organization)	*(I.R.S. Employer Identification No.)*
1911 Walker Avenue Monrovia, California	**91016**
(Address of principal executive offices)	*(Zip Code)*

(626)303-7902
(Registrant s telephone number, including area code)
Securities registered pursuant to Section 12(b) of the Act:
None
Securities registered pursuant to Section 12(g) of the Act:
Common Stock, $.01 par value
(Title of class)

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. þ

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 of the registrant as of July 2, 2004, the last business day of the registrant s most recently completed second fiscal quarter, was approximately $153,394,326 based on the closing price per share of $7.51 of the registrant s Common Stock on that date.

The number of shares outstanding of the registrant s Common Stock as of March 25, 2005 was 20,690,638.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant s definitive proxy statement relating to its 2005 annual meeting of stockholders, which will be filed with the Securities and Exchange Commission pursuant to Regulation 14A within 120 days of the close of the registrant s last fiscal year, are incorporated by reference into Part III of this report.

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EXPLANATORY NOTE

STAAR Surgical Company (the Company) is filing this Amendment No. 1 to its Annual Report on Form 10-K for the year ended December 31, 2004 (the Report) to update the financial statements and related disclosures to reflect the Company s receipt, on April 4, 2005, of $13.5 million in net proceeds from the private placement of shares of the Company s common stock (the Private Placement). As a result of the Private Placement, the Company s independent registered public accounting firm has re-issued its opinion on the Company s financial statements to remove a qualifying paragraph that expressed substantial doubt about the Company s ability to continue as a going concern. The financing is described in this Amended Report under *Item 7. Management s Discussion and Analysis of Financial Condition and Results of Operations* and in the *Notes to Consolidated Financial Statements Note 19- Subsequent Event.*

The following sections of the Amended Report have been revised or added to reflect the removal of the independent registered public accounting firm s qualification:

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

Report of Independent Registered Public Accounting Firm;

Note 1 to Consolidated Financial Statements of the Company;

Note 19 to Consolidated Financial Statements of the Company; and

Independent Registered Public Accounting Firm Report on Schedule.

Additionally, on April 14, 2005, the SEC announced a new rule that delays the implementation of FASB Statement No. 123 (revised 2004), *Share-Based Payment*, to the beginning of fiscal 2006. Descriptions of this new accounting pronouncement included in *Item 7. Management s Discussion and Analysis of Financial Condition and Results of Operations* and the *Notes to Consolidated Financial Statements Note 1 Significant Accounting Policies* have been updated to reflect this change.

While the remainder of the report is unchanged, the Company is reproducing the Report in its entirety to provide a complete presentation to the reader. This Amendment No. 1 speaks as of the original date of the filing date of the Report, except for certifications, which speak as of their respective dates and the filing date of this Amendment No. 1. Except as specifically indicated, the Report has not been updated to reflect events occurring subsequently to the original filing date.

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PART I

This Annual Report on Form 10-K contains statements which constitute forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. These statements include comments regarding the intent, belief or current expectations of the Company and its management. Prospective investors are cautioned that any such forward-looking statements are not guarantees of future performance and involve risks and uncertainties, and that actual results may differ materially from those projected in the forward-looking statements. See Item 7. Management s Discussion and Analysis of Financial Condition and Results of Operations Risk Factors.

Item 1. *Business*

General

STAAR Surgical Company develops, manufactures and distributes worldwide products used by ophthalmologists and other eye care professionals to improve or correct vision in patients with cataracts, refractive conditions, and glaucoma. Originally incorporated in California in 1982, STAAR Surgical Company reincorporated in Delaware in 1986. Unless the context indicates otherwise we, us, the Company, and STAAR refer to STAAR Surgical Company and its consolidated subsidiaries.

Cataract Surgery. Our main products are foldable silicone and Collamer® intraocular lenses (IOLs) used after minimally invasive small incision cataract extraction. Over the years, we have expanded our range of products for use in cataract surgery to include:

- the Preloaded Injector, a three-piece silicone IOL preloaded into a single-use disposable injector,
- toric silicone IOLs to treat astigmatic abnormalities,
- STAARVISC™ II, a viscoelastic material which is used as a tissue protective lubricant and to maintain the shape of the eye during surgery,
- STAAR SonicWAVE™ Phacoemulsification System, which is used to remove a cataract patient s cloudy lens and has low energy and high vacuum characteristics, and
- Cruise Control, a disposable filter which allows for a significantly faster, cleaner phacoemulsification procedure and is compatible with all phacoemulsification equipment utilizing Venturi and peristaltic pump technologies.

Currently, the majority of our revenues are generated from these products.

Refractive Surgery. In the area of refractive surgery, we have used our biocompatible Collamer material to develop and manufacture the Visian™ ICL (ICL) and the Visian™ TICL (TICL) to treat refractive disorders such as myopia (near-sightedness), hyperopia (far-sightedness) and astigmatism. These disorders of vision affect a large proportion of the population. Unlike the intraocular lens (IOL), which replaces a cataract patient s cloudy lens, these products are designed to work with the patient s natural lens to correct refractive errors. The Company s goal is to establish the ICL and TICL as the next paradigm shift in refractive surgery, making the products significant revenue generators for the Company over the next four to five years.

The ICL and TICL have not yet been approved for use in the United States. If approved, we believe that the ICL will have a significant market as an alternative to LASIK and other available refractive surgical procedures and could replace cataract surgery products as STAAR s largest source of revenue. The ICL is approved for use in the European Union and in Korea and Canada. The TICL is approved for use in the European Union. For a discussion of the status of the FDA review of the ICL, see Regulatory Matters FDA Review of the ICL.

Glaucoma Surgery. We have also developed the AquaFlow™ Collagen Glaucoma Drainage Device (the Aqua Flow Device), as an alternative to current methods of treating open-angle glaucoma. The

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AquaFlow Device is implanted in the sclera (the white of the eye), using a minimally invasive procedure, for the purpose of reducing intraocular pressure.

Within each of these segments, we also sell other instruments, devices and equipment that we manufacture or that are manufactured by others in the ophthalmic industry. In general, these products complement STAAR s proprietary product range and allow us to compete more effectively.

Recent Developments

For a description of financial and other recent developments, see Management s Discussion and Analysis of Financial Condition and Results of Operations Overview.

Strategy

Our mission is to develop, manufacture and distribute worldwide visual implants and other ophthalmic products that improve the vision of patients with cataracts, refractive conditions and glaucoma. The key elements of the Company s strategy are as follows:

Expanding the market for the ICL. We are seeking to expand the market for our ICL and TICL by the following means:

obtaining the approval of the FDA to market the ICL and the TICL in the United States;

obtaining the approval of the ICL and the TICL in new international markets; and

expanding the market share of the ICL and the TICL in existing international markets.

Revitalizing our IOL business. We are seeking to rebuild the market share of our IOLs in the United States by the following means:

increasing the awareness of ophthalmologists of the advantages of our proprietary Collamer material as an alternative to either silicone or acrylic for the manufacture of IOLs;

improving the injector systems for our lenses; and

obtaining U.S. approval for our preloaded injector technology and expanding it to all of our lenses.

Improving regulatory compliance. We are seeking to improve our quality systems to correct any deficiencies identified in the FDA s December 22, 2003 Warning Letter and the 483 Observations. For a description of these regulatory issues, see Regulatory Matters Warning Letters and the 483 Observations.

Reducing operating expenses and seeking additional financing. During late 2004 and early 2005, we took steps to reduce our operating expenses by, among other things, reducing our use of independent consultants and reducing our direct sales force. In addition, we are seeking additional financing. See Management s Discussion and Analysis of Financial Condition and Results of Operations Risk Factors We have only limited working capital and We have only limited access to financing.

Financial Information about Segments and Geographic Areas

The Company has expanded its marketing focus beyond the cataract surgery market to include the refractive surgery and glaucoma markets. However, during 2004 the cataract segment accounted for 90.4% the majority of the Company s revenues and, thus, the Company operates as one business segment for financial reporting purposes. See Note 17 to the Consolidated Financial Statements for financial information about product lines and operations in geographic areas.

Background

The human eye is a specialized sensory organ capable of receiving visual images that are transmitted to the visual center in the brain. The main parts of the eye are the cornea, the iris, the lens, the retina, and the

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trabecular meshwork. The cornea is the clear window in the front of the eye through which light first passes. The iris is a muscular curtain located behind the cornea which opens and closes to regulate the amount of light entering the eye through the pupil, an opening at the center of the iris. The lens is a clear structure located behind the iris that changes shape to better focus light to the retina, located in the back of the eye. The retina is a layer of nerve tissue consisting of millions of light receptors called rods and cones, which receive the light image and transmit it to the brain via the optic nerve. The anterior chamber of the eye, located in front of the iris, is filled with a watery fluid called the aqueous humour, while the portion of the eye behind the lens is filled with a jelly-like material called the vitreous humour. The trabecular meshwork, a drainage channel located between the iris and the surrounding white portion of the eye, maintains a normal pressure in the anterior chamber of the eye by draining excess aqueous humour.

The eye can be affected by common visual disorders, disease or trauma. The most prevalent ocular disorders or diseases are cataracts and glaucoma. Cataract formation is generally an age related situation that involves the hardening and loss of transparency of the natural crystalline lens, impairing visual acuity.

Glaucoma is a progressive ocular disease that manifests itself through increased intraocular pressure. This, in turn, may result in damage to the optic disc and a decrease of the visual field. Untreated, progressive glaucoma can result in blindness.

Refractive disorders include myopia, hyperopia, astigmatism and presbyopia. Myopia and hyperopia are caused by either overly curved or flat corneas which result in improper focusing of light on the retina. They are also known as near-sightedness and far-sightedness, respectively. Astigmatism is characterized by an irregularly shaped cornea resulting in blurred vision. Presbyopia is an age related condition caused by the loss of elasticity of the natural crystalline lens, reducing the eye s ability to accommodate or adjust for varying distances.

Principal Products

Our products are designed to:

Improve patient outcomes,

Minimize patient risk and discomfort, and

Simplify ophthalmic procedures or post-operative care for the surgeon and the patient.

Intraocular Lenses (IOLs) and Related Cataract Treatment Products. We produce and market a line of foldable IOLs for use in minimally invasive cataract surgical procedures. Our IOLs can be folded, and therefore can be implanted into the eye through an incision as small as 2.8 mm. Once inserted, the IOL unfolds naturally to replace the cataractous lens.

In late 2003, we introduced, through our joint venture company, Canon Staar, the first preloaded lens injector system in international markets. We believe the Preloaded Injector offers surgeons improved convenience and reliability. The Preloaded Injector is not yet available in the U.S.

Currently, our foldable IOLs are manufactured from both our proprietary Collamer material and silicone. Both materials are offered in two differently configured styles, the single-piece plate haptic design and the three-piece design where the optic is combined with polyimide loop haptics. The selection of one style over the other is primarily based on the preference of the ophthalmologist. The Collamer IOL is offered in a single-piece design. A redesign of the three-piece version of the lens has been completed along with a dedicated injection system which is in the final stages of development.

We have developed and currently market globally the Toric IOL, a toric version of our single-piece silicone IOL, which is specifically designed for patients with pre-existing astigmatism. The Toric IOL is the first refractive product we offered in the U.S.

Sales of foldable IOLs accounted for approximately 56% of our total revenues for the 2004 fiscal year, 61% of total revenues for the 2003 fiscal year and 65% of total revenues for the 2002 fiscal year.

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As part of our approach to providing complementary products for use in minimally invasive cataract surgery, we also market STAARVISC II, a viscoelastic material which is used as a protective lubricant and to maintain the shape of the eye during surgery, the STAAR SonicWAVE Phacoemulsification System, which is used to remove a cataract patient s cloudy lens and has low energy and high vacuum characteristics, and Cruise Control, a single-use disposable filter which allows for a significantly faster, cleaner phacoemulsification procedure and is compatible with all phacoemulsification equipment utilizing Venturi and peristaltic pump technologies. We also sell other related instruments, devices, surgical packs and equipment that we manufacture or that are manufactured by others. Sales of other cataract products accounted for approximately 32% of our total revenues for the 2004 fiscal year, 29% of total revenues for the 2003 fiscal year and 26% of total revenues for the 2002 fiscal year.

AquaFlow Collagen Glaucoma Drainage Device. Our AquaFlow Device is surgically implanted in the outer tissues of the eye to maintain a space that allows increased drainage of intraocular fluid so as to reduce intraocular pressure. It is made of collagen, a porous material that is compatible with human tissue and facilitates drainage of excess eye fluid. The AquaFlow Device is specifically designed for patients with open-angled glaucoma, which is the most prevalent type of glaucoma. In contrast to conventional and laser glaucoma surgeries, implantation of the AquaFlow Device does not require penetration of the anterior chamber of the eye. Instead, a small flap of the outer eye is folded back and a portion of the sclera and trabecular meshwork is removed. The AquaFlow Device is placed above the remaining trabecular meshwork and Schlemm s canal and the outer flap is refolded into place. The device swells, creating a space as the eye heals. It is absorbed into the surrounding tissue within six months to nine months after implantation, leaving the open space and possibly creating new fluid collector channels. The 15 to 45 minute surgical procedure to implant the AquaFlow Device is performed under local or topical anesthesia, typically on an outpatient basis.

While we believe the glaucoma market is very conservative, there is a continuing interest in learning the surgical procedure to implant the AquaFlow Device. Adoption by ophthalmic surgeons, however, will be dependent upon the rate at which they learn to perform the surgical procedure or the development of instrumentation to simplify the procedure. Sales of AquaFlow Devices accounted for approximately 2% of our total revenues in each of the 2004, 2003, and 2002 fiscal years.

Refractive Correction Visian ICL™ (ICLs). ICLs are implanted into the eye in order to correct refractive disorders such as myopia, hyperopia and astigmatism. Lenses of this type are generically called phakic IOLs or phakic implants because they work along with the patient s natural lens, or *phakos*, rather than replacing it. The ICL is capable of correcting a wide range of refractive disorders from low to severe conditions.

The ICL is folded and implanted into the eye behind the iris and in front of the natural crystalline lens using minimally invasive surgical techniques similar to implanting an IOL during cataract surgery, except that the human lens is not removed. The surgical procedure to implant the ICL is typically performed with topical anesthesia on an outpatient basis. Visual recovery is within one to 24 hours.

We believe the ICL will complement current refractive technologies and allow refractive surgeons to expand their treatment range and customer base.

The ICL and TICL have not yet been approved for use in the United States. The ICL for myopia is approved for use in the European Union and in Korea and Canada, and applications are pending in Australia. The TICL is approved for use in the European Union, and applications are pending in Australia, Korea and Canada. The Company has completed enrollment in the U.S. clinical trials for the TICL and expects to file its submission with the FDA in late 2005. For a discussion of the status of the FDA review of the ICL, see Regulatory Matters FDA Review of the ICL.

The Hyperopic ICL is approved for use in the European Union and in Canada, and is currently in clinical trials in the United States.

The ICL is available internationally for myopia in five lengths, with 41 powers for each length, and for hyperopia in five lengths, with 38 powers for each length, which equates to approximately 400 inventoried parts. This requires the Company to carry a significant amount of inventory to meet the customer demand for

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rapid delivery. The Toric ICL is available for myopia in the same powers and lengths but carries additional parameters of cylinder and axis with 11 and 180 possibilities, respectively. As such, the Toric ICL is made to order.

Sales of ICLs accounted for approximately 8% of our total revenues for the 2004 fiscal year, 6% of total revenues for the 2003 fiscal year and 5% of total revenues for the 2002 fiscal year.

Sources and Availability of Raw Materials

The Company uses a wide range of raw materials in the production of our products. Most of the raw materials and components are purchased from external suppliers. Some of our raw materials are single-sourced due to regulatory constraints, cost effectiveness, availability, quality, and vendor reliability issues. Many of our components are standard parts and are available from a variety of sources although we do not typically pursue regulatory and quality certification of multiple sources of supply. With the exception of our silicone material, we do not believe that the loss of any existing external supply source would have material adverse effect on us.

The proprietary collagen-based raw material used to manufacture our IOLs, ICLs and the AquaFlow Device is internally sole-sourced from one of our facilities in California. If the supply of these collagen-based raw materials is disrupted we know of no alternative supplier, and therefore, any such disruption could result in our inability to manufacture the products and would have a material adverse effect on the Company.

Patents, Trademarks and Licenses

We strive to protect our investment in the research, development, manufacturing and marketing of our products through the use of patents, licenses, trademarks, and copyrights. We own or have rights to a number of patents, licenses, trademarks, copyrights, trade secrets and other intellectual property directly related and important to our business. As of December 31, 2004, we owned approximately 84 United States and foreign patents and had approximately 66 patent applications pending.

We believe that our patents are important to our business. Of significant importance to the Company are the patents, licenses, and technology rights surrounding our Visian ICL (ICL) and Collamer material. In 1996, we were granted an exclusive royalty- bearing license to manufacture, use, and sell ICLs in the United States, Europe, Latin America, Africa, and Asia using the uniquely biocompatible Collamer material. The Collamer material is also used in certain of our IOLs. We have also acquired or applied for various patents and licenses related to our Aqua Flow Device, our phacoemulsification system, our insertion devices, and other technologies of the Company.

Patents for individual products extend for varying periods of time according to the date a patent application is filed or a patent is granted and the term of patent protection available in the jurisdiction granting the patent. The scope of protection provided by a patent can vary significantly from country to country.

Our strategy is to develop patent portfolios for our research and development projects in order to obtain market exclusivity for our products in our major markets. Although the expiration of a patent for a product normally results in the loss of market exclusivity, we may continue to derive commercial benefits from these products. We routinely monitor the activities of our competitors and other third parties with respect to their use of intellectual property, including considering whether or not to assert our patents where we believe they are being infringed.

Worldwide, all of our major products are sold under trademarks we consider to be important to our business. The scope and duration of trademark protection varies widely throughout the world. In some countries, trademark protection continues only as long as the mark is used. Other countries require registration of trademarks and the payment of registration fees. Trademark registrations are generally for fixed but renewable terms.

We protect our proprietary technology, in part, through confidentiality and nondisclosure agreements with employees, consultants and other parties. Our confidentiality agreements with employees and consultants

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generally contain standard provisions requiring those individuals to assign to STAAR, without additional consideration, inventions conceived or reduced to practice by them while employed or retained by STAAR, subject to customary exceptions.

Seasonality

We experience some seasonality in demand for our products with sales in the third quarter generally being the lowest due to the impact of summer vacations on elective surgeries.

Distribution and Customers

We market our products to a variety of health care providers, including surgical centers, hospitals, managed care providers, health maintenance organizations, group purchasing organizations and government facilities. The primary user of our products is the ophthalmologist. No material part of our business, taken as a whole, is dependant upon a single or a few customers.

We maintain direct distribution to the physician or facility in the United States, Canada, Germany and Australia. Sales efforts in Germany and Australia are primarily supported through a direct sales force. Sales efforts in the United States and Canada are primarily supported through a network of independent manufacturers representatives. The independent representatives are compensated through the payment of commissions based on sales and may represent manufacturers other than STAAR, although not in competing products. In all other countries where we do business, we sell principally through independent distributors.

We support the sales efforts of our agents, employees and distributors through the activities of our internal marketing department. Sales efforts are supplemented through the use of promotional materials, educational courses, speakers programs, participation in trade shows and technical presentations.

The dollar amount of the Company s backlog orders is not significant in relation to total annual sales. The Company generally keeps sufficient inventory on hand to ship product when ordered.

Competitive Conditions

Competition in the ophthalmic medical device field is intense and characterized by extensive research and development and rapid technological change. Development by competitors of new or improved products, processes or technologies may make our products obsolete or less competitive. We will be required to devote continued efforts and significant financial resources to enhance our existing products and to develop new products for the ophthalmic industry.

We believe our primary competition in the development and sale of products used to surgically correct cataracts, namely foldable IOLs and phacoemulsification machines, includes Alcon Laboratories, Advanced Medical Optics (AMO), and Bausch & Lomb. Currently, Alcon holds 48.2% of the U.S. IOL market, followed by AMO with 30.4% and Bausch & Lomb with 10.7%. We hold approximately 6.1% of the U.S. IOL market. Our competitors have been established for longer periods of time than we have and have significantly greater resources than we have, including greater name recognition, larger sales operations, greater ability to finance research and development and proceedings for regulatory approval, and more developed regulatory compliance and quality control systems.

In the U.S. market, physicians prefer IOLs made out of acrylic. Acrylic IOLs currently account for a 53.8% share of the U.S. IOL market. We believe that we are positioned to compete effectively in this market segment with the Collamer IOL, and that the introduction of the three-piece Collamer IOL will strengthen our position and allow for a gain in overall IOL market share. Silicone IOLs, which currently account for 42% of the U.S. market, also provide an opportunity for us as we introduce improvements in silicone IOL technology and Collamer IOL injection systems to facilitate delivery of the IOL.

Our primary competition in the development and sale of products used to treat glaucoma is from pharmaceutical companies, primarily because drug therapy is, and for years has been, the accepted treatment for glaucoma. The portion of this market held by medical devices used to treat glaucoma is insignificant at

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present. We believe that Merck & Company, Pfizer, Novartis, Alcon, Allergan and Bausch & Lomb are the largest providers of drugs used to treat glaucoma. There are also devices under development by others to be used in conjunction with a non-penetrating deep sclerectomy for the surgical management of glaucoma.

Our ICL will face significant competition in the marketplace from products that improve or correct refractive conditions, such as corrective eyeglasses, external contact lenses, and conventional and laser refractive surgical procedures. These are products long established in the marketplace and familiar to patients in need of refractive correction. Furthermore, corrective eyeglasses and external contact lenses are more easily obtained, in that a prescription is usually written following a routine eye examination in a doctor s office, without admitting the patient to a hospital or surgery center.

We believe that the following providers of laser surgical procedures comprise our primary competition in the marketplace for patients requiring refractive corrections: Alcon, Bausch & Lomb, VISX, Nidek and Wave Light all market Excimer lasers for corneal refractive surgery. Approval of custom ablation, along with the addition of wavefront technology, has increased awareness of corneal refractive surgery by patients and practitioners. Conductive Keratoplasty (CK) by Refractec competes for the hyperopic market for +1.0 to +3.0 diopters. In the phakic IOL market, the ICL faces the Ophtec Verisyse or Artisan IOL, distributed in the United States by AMO, IOLTech s PRL, as well as phakic IOLs under investigation by Ophthalmic Innovations International, Tekia, Alcon, Vision Membrane and ThinOptX.

Regulatory Matters

Regulatory Requirements

Our products are subject to regulatory approval in the United States and in foreign countries. We are also subject to various federal, state, local and foreign laws applicable to our operations including, among other things, working conditions, laboratory and manufacturing practices, and the use and disposal of hazardous or potentially hazardous substances.

The following discussion outlines the various kinds of reviews to which our products or production facilities may be subject.

Regulatory Requirements in the United States. Under the federal Food, Drug & Cosmetic Act as amended by the Food and Drug Administration Modernization Act of 1997 (the Act), the FDA has the authority to adopt regulations that:

- set standards for medical devices,
- require proof of safety and effectiveness prior to marketing devices which the FDA believes require pre-market clearance,
- require test data approval prior to clinical evaluation of human use,
- permit detailed inspections of device manufacturing facilities,
- establish good manufacturing practices that must be followed in device manufacture,
- require reporting of serious product defects to the FDA, and
- prohibit device exports that do not comply with the Act unless they comply with established foreign regulations, do not conflict with foreign laws, and the FDA and the health agency of the importing country determine export is not contrary to public health.

Most of our products are medical devices intended for human use within the meaning of the Act and, therefore, are subject to FDA regulation.

The FDA establishes procedures for compliance based upon regulations that designate devices as Class I (general controls, such as labeling and record-keeping requirements), Class II (performance standards in addition to general

controls) or Class III (pre-market approval (PMA) before commercial marketing). Class III devices are the most extensively regulated because the FDA has determined they are life-supporting,

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are of substantial importance in preventing impairment of health, or present a potential unreasonable risk of illness or injury. The effect of assigning a device to Class III is to require each manufacturer to submit to the FDA a PMA that includes information on the safety and effectiveness of the device.

A medical device that is substantially equivalent to a directly related medical device previously in commerce may be eligible for the FDA s pre-market notification 510(k) review process. FDA 510(k) clearance is a grandfather process. As such, FDA clearance does not imply that the safety, reliability and effectiveness of the medical device has been approved or validated by the FDA, but merely means that the medical device is substantially equivalent to a previously cleared commercial medical device. The review period and FDA determination as to substantial equivalence generally is made within 90 days of submission of a 510(k) application, unless additional information or clarification or clinical studies are requested or required by the FDA. As a practical matter, the review process and FDA determination may take longer than 90 days.

Our IOLs and ICLs are Class III devices, our AquaFlow Devices, phacoemulsification equipment, ultrasonic cutting tips and surgical packs are Class II devices, and our lens injectors are Class I devices. We have received FDA pre-market approval for our IOLs (including the toric and the Collamer IOLs) and AquaFlow Device and 510(k) clearance for our phacoemulsification equipment, lens injectors, and ultrasonic cutting tips.

As a manufacturer of medical devices, our manufacturing processes and facilities are subject to continuing review by the FDA and various state agencies to ensure compliance with quality system regulations. These agencies inspect our facilities from time to time to determine whether we are in compliance with various regulations relating to manufacturing practices, validation, testing, quality control and product labeling.

Regulatory Requirements in Foreign Countries. There is a wide variation in the approval or clearance requirements necessary to market medical products in foreign countries. The requirements range from minimal requirements to requirements comparable to those established by the FDA. For example, many countries in South America have minimal regulatory requirements, while many developed countries, such as Japan, have requirements at least as stringent as those of the FDA. Foreign governments do not always accept FDA approval as a substitute for their own approval or clearance procedures.

As of June 1998, the member countries of the European Union (the Union) require that all medical products sold within their borders carry a Conformite Europeane Mark (CE Mark). The CE Mark denotes that the applicable medical device has been found to be in compliance with guidelines concerning manufacturing and quality control, technical specifications and biological or chemical and clinical safety. The CE Mark supersedes all current medical device regulatory requirements for Union countries. We have obtained the CE Mark for all of our principal products including our ICL and TICL, IOLs (including the Toric IOL and Collamer IOL), SonicWAVE Phacoemulsification System and our AquaFlow Device.

Warning Letters and the 483 Observations

The Company received a Warning Letter issued by the FDA, dated December 22, 2003 which outlined deficiencies related to the manufacturing and quality assurance systems of its Monrovia, California facility. To assist it in correcting the issues raised in the Warning Letter, the Company engaged the services of Quintiles Consulting (Quintiles), a well regarded consulting organization that specializes in FDA related compliance matters. The Company, with Quintiles help, assessed the state of its quality system in light of the FDA s concerns, developed an improvement plan, and took corrective actions to improve the Company s processes, procedures, and controls.

The Company received a second Warning Letter from the FDA dated April 26, 2004, which outlined deficiencies noted in an audit by the FDA in December 2003. The Company provided the FDA with its planned corrective actions to the issues raised, and in a letter dated July 1, 2004, the FDA responded that they found the corrective and preventative action plans described in the Company s response adequate.

On June 17, 2004, the FDA completed an audit of the Company s Nidau, Switzerland manufacturing facility. The FDA did not observe any violations of quality system requirements during this audit.

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On September 23, 2004, as a follow-up to the December 22, 2003 Warning Letter, the FDA completed a re-audit of the Company s Monrovia, California manufacturing facility. At the conclusion of the audit, the FDA issued a form FDA 483 Inspectional Observations described more fully in the Company s Current Report on Form 8-K filed with the Securities and Exchange Commission on September 29, 2004 (the 483 Observations). The Company delivered its response to the FDA on November 5, 2004. On January 27, 2005, the Company and its representatives met with the FDA to update them on the corrective actions taken by the Company in response to the 483 Observations. During the meeting, the FDA gave no indication of the status of their review of the response or the nature or timing of future communications to the Company. However, subsequent to the meeting the FDA confirmed with the Company s regulatory counsel, with respect to issues relating to the Collamer material addressed in the 483 Observations, that materials issues with regard to stability have been addressed to the FDA s satisfaction.

Until the FDA is satisfied with the adequacy of the Company s corrective actions, it may take further actions which could include conducting another inspection, seizure of the Company s products, injunction of the Monrovia facility to compel compliance (which may include suspension of production operations and/or recall of products), or other actions. Such actions could have a material adverse effect on the Company s established lines of business, results of operations and liquidity.

The Company is not able to predict whether the FDA will conclude that the Company s corrective actions to date or those included in its response to the 483 Observations satisfactorily resolve its concerns. Nor can the Company predict the likelihood, nature of, or timing of any additional action by the FDA or the impact of any other FDA action on the Company s established lines of business, results of the operations or liquidity or the approval of the ICL for the United States market.

FDA Review of the ICL

On October 3, 2003, the FDA Ophthalmic Devices Panel recommended that, with certain conditions, the FDA approve the ICL for use in correcting myopia in the range of -3 to -15 diopters and reducing myopia in the range of -15 to -20 diopters. However, until the FDA is satisfied with the Company s corrective actions to the deficiencies identified in the December 22, 2003 Warning Letter and the 483 Observations, it is unlikely to grant the Company approval to market the ICL in the United States.

On December 16, 2004, the Company submitted to the FDA a supplement to the Company s investigational device exemptions application for the ICL. The supplement requested permission for each of the active clinical centers to continue enrollment of eyes in the ICL clinical investigation while the pre-market approval is pending with the FDA so that the physicians may continue to expand on their clinical experience with implantation of the ICL. On January 14, 2005, the FDA approved the supplement allowing 18 investigational sites to enroll a combined total of 75 additional eyes each month.

Research and Development

We are focused on furthering technological advancements in the ophthalmic products industry through the development of innovative ophthalmic products and materials and related surgical techniques. We maintain an active internal research and development program which includes research and development, clinical activities, and regulatory affairs and is comprised of 23 employees. In order to achieve our business objectives, we will continue the investment in research and development. Over the past year, we have principally focused our research and development efforts on:

improving regulatory and compliance systems and procedures,

obtaining approval for the ICL,

completing enrollment in the U.S. clinical trials for the TICL,

redesigning the three-piece Collamer IOL,

designing an insertion system for the three-piece Collamer IOL,

improving insertion and delivery systems for our other foldable products,

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improving manufacturing systems and procedures for all products to reduce manufacturing costs and improve yields, and

developing products and extending foreign registrations.

Research and development expenses were approximately $6,246,000, $5,120,000, and $4,016,000 for our 2004, 2003 and 2002 fiscal years, respectively.

Environmental Matters

The Company is subject to federal, state, local and foreign environmental laws and regulations. We believe that our operations comply in all material respects with applicable environmental laws and regulations in each country where we do business. We do not anticipate that compliance with these laws will have any material impact on our capital expenditures, earnings or competitive position. We currently have no plans to invest in material capital expenditures for environmental control facilities for the remainder of our current fiscal year or for the next fiscal year. We are not aware of any pending actions, litigation or significant financial obligations arising from current or past environmental practices that are likely to have a material adverse impact on our financial position. However, environmental problems relating to our properties could develop in the future, and such problems could require significant expenditures. Additionally, we are unable to predict changes in legislation or regulations that may be adopted or enacted in the future and that may adversely affect us.

Significant Subsidiaries

The Company s only significant subsidiary is STAAR Surgical AG, a wholly owned entity incorporated in Switzerland. This subsidiary develops, manufactures and distributes products worldwide including Collamer IOLs, ICLs, TICLs, and the AquaFlow Device. STAAR Surgical AG also controls 100% of Domilens GmbH, a European sales subsidiary that distributes both STAAR products and products from other ophthalmic manufacturers.

Canon Staar Joint Venture

In 1988, the Company entered into a joint venture with Canon Inc. and Canon Sales Co., Inc. for the principal purpose of designing, manufacturing, and selling in Japan intraocular lenses and other ophthalmic products. The joint venture will market its products worldwide through Canon, Canon Sales or STAAR or such other distributors as the Board of Directors of the joint venture may approve. The terms of any distribution arrangement will require the unanimous approval of the Board of Directors of the joint venture. Each joint venture party is entitled to appoint one member of the Board of Directors of the joint venture. Certain matters require the unanimous approval of the directors. Upon the occurrence of certain events, including the merger, sale of substantially all of the assets or change in the management of one of the parties, any of the other parties may have the right to acquire the first party s interest in the joint venture at book-value. The Company also granted to the joint venture a perpetual exclusive license under the Licensed Technology (as defined in the license agreement) to make and sell any products in Japan, and a perpetual non-exclusive license to do so in the rest of the world.

In 2001, the parties entered into a settlement agreement whereby (i) they reconfirmed the joint venture agreement and the license agreement, (ii) they agreed that the Company would promptly commence the transfer of the Licensed Technology to the joint venture, (iii) the Company granted the joint venture an exclusive license to make any products in China and sell such products in Japan and China (subject to the existing rights of third parties), (iv) the Company agreed to provide the joint venture with raw materials, (v) the joint venture granted Canon Sales Co., Inc. the right to distribute its products in Japan on specified terms, and (iv) the parties settled certain patent disputes.

The foregoing description of the joint venture agreement, technical assistance and license agreement and settlement agreement is qualified in its entirety by the full text of such agreements, which have been filed as exhibits or incorporated by reference to this report. See Management s Discussion and Analysis of Financial

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Condition and Results of Operations Risk Factors We have licensed our technology to our joint venture company and have granted certain rights to the partners that could be exercised in the event of a change in control of the Company.

Employees

As of February 25, 2005, we employed approximately 247 persons.

Additional Information

The Company makes available free of charge through our website, *www.staar.com,* our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) of the Securities Exchange Act of 1934, as soon as reasonably practicable after those reports are filed with or furnished to the Securities and Exchange Commission (SEC).

The public may read any of the items we file with the SEC at the SEC s Public Reference Room at 450 Fifth Street, NW, Washington, DC 20549. The public may obtain information about the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC also maintains an Internet site that contains reports, proxy and information statements, and other information regarding the Company and other issuers that file electronically with the SEC at http://www.sec.gov.

Item 2. ***Properties***

Our operations are conducted in leased facilities throughout the world. Our executive offices, manufacturing, warehouse and distribution, and primary research facilities are located in Monrovia, California. STAAR Surgical AG maintains office, manufacturing, and warehouse and distribution facilities in Nidau, Switzerland. The Company has one additional facility in Aliso Viejo, California for raw material production and research and development activities. The Company leases additional sales and distribution facilities in Germany and Australia. We believe our manufacturing facilities in the U.S. and Switzerland are suitable and adequate for our current and future planned requirements. The Company could increase capacity by adding additional shifts at our existing facilities. However, the Company is at capacity in the U.S. and Switzerland in the area of administration. The Company would require additional space to support growth in those areas, although this is not anticipated for 2005.

Item 3. ***Legal Proceedings***

We are currently party to various claims and legal proceedings arising out of the normal course of our business. These claims and legal proceedings relate to contractual rights and obligations, employment matters, and claims of product liability. We do not believe that any of the claims known to us is likely to have a material adverse effect on our financial condition or results of operations.

Since September 1, 2004, multiple class action lawsuits have been filed in the United States District Courts for the Central District of California and the District of New Mexico against the Company and its Chief Executive Officer on behalf of all persons who acquired the Company s securities during various periods between April 3, 2003 and September 28, 2004. On December 15, 2004, the Court ordered consolidation of the complaints that had been filed in the United States District Court for the Central District of California and directed that the plaintiffs file a consolidated complaint as soon as practicable. The plaintiffs have proposed a stipulation pursuant to which they would file a consolidated amended complaint on or about April 29, 2005. The New Mexico action was voluntarily dismissed on January 28, 2005. The lawsuits generally allege that the defendants violated Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, as amended, and Rule 10b-5 promulgated thereunder, by issuing false and misleading statements regarding intraocular lenses and implantable lenses, and failing timely to disclose significant problems with the lenses, as well as the existence of serious injuries and/or malfunctions attributable to the lenses, thereby artificially inflating the price of the Company s Common Stock. The plaintiffs generally seek to recover compensatory damages, including interest. The Company intends to vigorously defend the consolidated lawsuits.

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

There were no matters submitted to a vote of security holders during the quarter ended December 31, 2004.

PART II

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

Our Common Stock is quoted on the Nasdaq National Market under the symbol STAA. The following table sets forth the reported high and low bid prices of the Common Stock as reported by Nasdaq for the calendar periods indicated:

Period	High	Low
2005		
First Quarter (through March 25, 2005)	$ 7.300	$ 3.830
2004		
Fourth Quarter	$ 6.400	$ 3.500
Third Quarter	7.480	2.880
Second Quarter	9.730	6.250
First Quarter	11.260	7.230
2003		
Fourth Quarter	$ 12.000	$ 8.360
Third Quarter	15.440	9.750
Second Quarter	15.250	5.050
First Quarter	6.550	3.050

On March 25, 2005, the closing price of the Company s Common Stock was $3.95. Stockholders are urged to obtain current market quotations for the Common Stock.

As of March 25, 2005, there were approximately 565 record holders of our Common Stock.

We have not paid any cash dividends on our Common Stock since our inception. We currently expect to retain any earnings for use to further develop our business and not to declare cash dividends on our Common Stock in the foreseeable future. The declaration and payment of any such dividends in the future depends upon the Company s earnings, financial condition, capital needs and other factors deemed relevant by the Board of Directors and may be restricted by future agreements with lenders.

As of March 25, 2005, options to purchase 2,719,379 shares of Common Stock were exercisable.

Recent Sales of Unregistered Securites

On June 10, 2004, the Company sold 2,000,000 shares of Common Stock at a price per share of $6.25. The Company sold the shares of Common Stock directly, without the services of an underwriter, in a private placement made in reliance on Rule 506 of Regulation D under the Securities Act of 1933. The purchasers were all accredited investors within the meaning of Regulation D. The Company received proceeds, net of placement agent fees and other expenses, of approximately $11,646,000.

We also entered into a Registration Rights Agreement with the purchasers, in which we agreed to file a shelf registration statement under the Securities Act of 1933 providing for the public resale of their shares, and to keep the registration statement effective for up to two years. After the expiration of that two-year period, to the extent any of the investors have shares purchased in the 2004 private placement that are not eligible for public sale under Rule 144 or Regulation S, the investors may have a right under the Registration Rights Agreement to piggyback on other registered offerings of the Company to resell those shares.

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

The following table sets forth selected consolidated financial data with respect to the five most recent fiscal years ended December 31, 2004, January 2, 2004, January 3, 2003, December 28, 2001, and December 29, 2000. The selected consolidated statement of income data set forth below for each of the three most recent fiscal years, and the selected consolidated balance sheet data set forth below at December 31, 2004 and January 2, 2004, are derived from the consolidated financial statements which have been audited by BDO Seidman, LLP, independent certified public accountants, as indicated in their report which is included elsewhere in this Annual Report. The selected consolidated statement of income data set forth below for each of the two fiscal years in the periods ended December 28, 2001, and December 29, 2000, and the consolidated balance sheet data set forth below at January 3, 2003, December 28, 2001 and December 29, 2000 are derived from the Company s audited consolidated financial statements not included in this Annual Report. The selected consolidated financial data should be read in conjunction with the consolidated financial statements of the Company, and the Notes thereto, included elsewhere in this Annual Report, and Management s Discussion and Analysis of Financial Condition and Results of Operations in Item 7.

	Fiscal Year Ended				
	December 31, 2004	January 2, 2004	January 3, 2003	December 28, 2001	December 29, 2000
	(In thousands except per share data)				
Statement of Operations					
Sales	$ 51,685	$ 50,409	$ 47,880	$ 50,237	$ 53,986
Royalty and other income		49	368	549	448
Total revenues	51,685	50,458	48,248	50,786	54,434
Cost of sales	25,542	22,621	24,099	28,203	26,329
Gross profit	26,143	27,837	24,149	22,583	28,105
Selling, general and administrative expenses					
General and administrative	9,253	9,343	8,959	8,746	8,593
Marketing and selling	20,302	19,509	16,833	20,043	21,254
Research and development	6,246	5,120	4,016	3,800	4,215
Other charges	500	390	1,454	7,780	15,276
Total selling, general and administrative expenses	36,301	34,362	31,262	40,369	49,338
Operating loss	(10,158)	(6,525)	(7,113)	(17,786)	(21,233)
Total other expense, net	(88)	(637)	(785)	(724)	(4,630)
Loss before income taxes and minority interest	(10,246)	(7,162)	(7,898)	(18,510)	(25,863)
Income tax provision (benefit)	1,057	1,127	8,805	(3,649)	(6,758)
Minority interest	29	68	75	139	87

Net loss	$ (11,332)	$ (8,357)	$ (16,778)	$ (15,000)	$ (19,192)
Basic net loss per share	$ (0.58)	$ (0.47)	$ (0.98)	$ (0.88)	$ (1.25)
Diluted net loss per share	$ (0.58)	$ (0.47)	$ (0.98)	$ (0.88)	$ (1.25)
Weighted average number of basic shares	19,602	17,704	17,142	17,003	15,378
Weighted average number of diluted shares	19,602	17,704	17,142	17,003	15,378
Balance Sheet Data					
Working capital	$ 19,103	$ 15,883	$ 7,095	$ 16,780	$ 24,153
Total assets	51,973	47,376	45,220	64,650	79,745
Notes payable and current portion of long-term debt	3,004	2,950	5,845	8,216	7,944
Stockholders equity	37,840	35,219	30,551	46,142	58,060

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

Except for the historical information contained in this Annual Report, the matters discussed in Management s Discussion and Analysis of Financial Condition and Results of Operations are forward-looking statements, the accuracy of which is necessarily subject to risks and uncertainties. Actual results may differ significantly from the discussion of such matters in the forward-looking statements. See Risk Factors.

In the discussion of the material changes in our financial condition and results of operations between the reporting periods in the consolidated financial statements, management has sought to identify and, in some cases, quantify, the factors that contributed to such material changes. However, quantifying these factors may involve the presentation of numerical measures that exclude amounts that are included in the most directly comparable measure calculated and presented in accordance with accounting principles generally accepted in the United States (GAAP). Management uses this information to assess material changes in our financial condition and results of operations and is providing it to assist investors and potential investors to understand these assessments. In each instance, such information is presented immediately following (and in connection with an explanation of) the most directly comparable financial measure calculated in accordance with GAAP, and includes other material information necessary to reconcile the information with the comparable GAAP financial measure.

Overview

STAAR Surgical Company develops, manufactures and distributes worldwide visual implants and other ophthalmic products to improve or correct the vision of patients with cataracts, refractive conditions, and glaucoma. Originally incorporated in California in 1982, STAAR Surgical Company reincorporated in Delaware in 1986. Unless the context indicates otherwise we, us, the Company, and STAAR refer to STAAR Surgical Company and its consolidated subsidiaries.

History

STAAR developed, patented, and licensed the first foldable intraocular lens, or IOL, for cataract surgery. Made of pliable material, the foldable IOL permitted surgeons for the first time to replace a cataract patient s natural lens with minimally invasive surgery. The foldable IOL quickly became the standard of care for cataract surgery throughout the world. STAAR introduced its first versions of the lens, made of silicone, in 1991.

In 1996, STAAR commenced commercial sales of its VISIAN™ ICL (ICL) in certain foreign countries, and in 1997, the ICL received CE Marking which allowed STAAR to market the product in the European Union. Using the unique biocompatible properties of the Collamer material, the ICL is implanted in front of the patient s natural lens to treat refractive errors, such as myopia (nearsightedness) and hyperopia (farsightedness). In 2003, the ICL became the first phakic IOL to receive an approvable recommendation from the FDA s Ophthalmic Devices Panel. Currently, the ICL is approved for sale in 38 countries and has been implanted in approximately 40,000 eyes worldwide.

In 1998, STAAR introduced the Toric IOL, the only implantable lens approved for the treatment of astigmatism. The Toric IOL was STAAR s first venture into the refractive market in the United States.

In 2000, STAAR introduced an IOL made of our proprietary Collamer® lens material, a unique biocompatible polymerized collagen. Collamer mimics the clarity and refractive qualities of the natural human lens better than acrylic lens materials, and is better tolerated by the eye than either silicone or acrylic.

In 2001, STAAR commenced commercial sales of its VISIAN™ Toric ICL (TICL) on a limited basis in certain foreign countries, and in 2002, the TICL received CE Marking which allowed STAAR to market the product in the European Union.

In 2004, STAAR, through its joint venture company, Canon Staar, introduced the first preloaded lens injector system in international markets. The Preloaded Injector offers surgeons improved convenience and reliability.

The Preloaded Injector is not yet available in the U.S.

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Principal Products

Cataract Surgery. The production and sale of IOLs for use in cataract surgery remains our core business. Our products for cataract surgery include the following:

Silicone IOLs, in both three-piece and one-piece designs;

Silicone Toric IOLs, used in cataract surgery to treat astigmatism;

Collamer® IOLs, in a one-piece design, with a three-piece redesigned lens scheduled for introduction in the second quarter of 2005;

the Preloaded Injector, a three-piece silicone IOL preloaded into a single-use disposable injector;

STAARVISC[tm] II, a viscoelastic material, which is used as a tissue protective lubricant and to maintain the shape of the eye during surgery;

SonicWAVE[tm] Phacoemulsification System, which is used to remove a cataract patient s cloudy lens and has low energy and high vacuum characteristics;

Cruise Control, a disposable filter used to increase safety and control during phacoemulsification; and

Other auxiliary products for cataract surgery, manufactured by others, which strengthen our ability to offer an expanded range of procedural products.

Sales of cataract surgery products accounted for approximately 90% of our total revenues for the year ended December 31, 2004 and 92% for the 2003 fiscal year.

Refractive Surgery. We have used our unique biocompatible Collamer material to develop and manufacture lenses to treat refractive disorders such as myopia (near-sightedness), hyperopia (far-sightedness) and astigmatism. These include the VISIAN[tm] ICL, or ICL®, and the Toric VISIAN[tm] TICL, or TICL®. Lenses of this type are generically called phakic IOLs or phakic implants because they work along with the patient s natural lens, or *phakos*, rather than replacing it.

The ICL and TICL have not yet been approved for use in the United States. The ICL is approved for use in the European Union and in Korea and Canada. The TICL completed enrollment in clinical trials in the United States in early 2005, and is approved for use in the European Union.

Glaucoma Surgery. We have developed the AquaFlow[tm] Collagen Glaucoma Drainage Device, also referred to as the AquaFlow Device, as an alternative to current methods of treating open angle glaucoma. The AquaFlow Device is implanted in the sclera (the white of the eye), using a minimally invasive procedure, for the purpose of reducing intraocular pressure.

Significant Factors Affecting Our Business and Recent Highlights

Changing Focus of Research and Development. STAAR s executive management was completely replaced commencing in 2001. The new management team assumed control of a company with a long record of innovation in ophthalmology, but one that had failing financial results and was expending cash at a significant rate. STAAR was also embroiled in several legal actions which affected our cash reserves. The new management implemented significant restructuring and other cost-cutting measures in 2001 to conserve our cash resources. Despite these cutbacks, STAAR has continued to devote a significant amount of its resources to developing and introducing the ICL.

Because of its significant investment in ICL technology, STAAR had limited resources for further developing its mature and well accepted IOL products for cataract treatment. Nevertheless, in the fourth quarter of 2003, the Company introduced the first preloaded injector system which was developed by its joint venture company in Japan, Canon Staar. Management believes, however, that during the long process of developing and seeking approval for the ICL, STAAR overall failed to match some of its competitors improvements to IOL technology and standard delivery

systems resulting in a loss of U.S. market share.

As U.S. approval of the ICL appeared more likely in late 2003, and the focus of the ICL project shifted from development to marketing, management began to devote research and development resources to making STAAR s IOL delivery systems more competitive. In an effort to strengthen the areas of research and

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development, we separated our research and development function from our regulatory and compliance function and hired Tom Paul, PhD as Vice President, Research and Development and James Farnworth as Vice President, Regulatory and Quality Assurance. The resources for these efforts were made available by STAAR s 2003 private sale of Common Stock, the proceeds of which were intended to fund the launching and marketing of the ICL.

The Warning Letter received from the FDA on December 29, 2003 caused STAAR to accelerate its efforts to improve its quality and regulatory compliance systems. The delay in the approval of the ICL until compliance issues were resolved further accelerated the need to invest in improvements to its IOL delivery systems in order to maintain its core cataract business.

As a result of the above factors and the receipt of a second Warning Letter, 2004 saw significant new investments in the restructuring of STAAR s quality assurance and regulatory compliance functions, and in improving IOL technology, particularly lens delivery systems. While some R&D expense is directly attributable to the response to the FDA s Warning Letters and related audits of STAAR s facilities, the bulk of the expense results from systemic changes intended to produce a permanent improvement in the areas of research and development and quality assurance and regulatory compliance.

As described below, the initiative to improve IOL delivery technology resulted in progress towards the completion of an improved one-piece Collamer IOL injector, continuous improvement efforts to cartridge injector components for all lenses and a redesigned three-piece Collamer IOL injector. The continuous effort to improve cartridges resulted in supply problems, particularly in the second quarter of 2004. The timing of this interruption in supply, which coincided with increased R&D expenditures and a decline in sales of silicone IOLs, contributed to the drop in earnings in the second quarter. The decision to upgrade our three-piece Collamer lens design to coincide with the introduction of the first dedicated injector for this lens, coupled with a revised quality system, have resulted in the combined introduction being delayed.

Contraction of Silicone IOL Market. Our market share for silicone IOLs has steadily decreased over the last several years, as many surgeons now choose lenses made of acrylic material rather than silicone for their patients. Management believes that Collamer lens material will ultimately be competitive with acrylic, but to date sales of Collamer IOLs have only partially offset declining sales of silicone IOLs.

Redesign of Injectors and Three-Piece Collamer IOL. In an effort to improve the competitiveness of our lens injection systems for Collamer IOLs, during 2004 we devoted significant resources to improving the injector for the one-piece Collamer IOL and redesigning the three-piece Collamer injector. The redesign of the three-piece Collamer injector resulted in a hiatus in three-piece Collamer lens production, which STAAR took as an opportunity to make minor improvements and enhancements to the lens design. As a result of these efforts, three-piece Collamer IOLs had limited availability during 2004.

Decline in U.S. Sales of IOLs. During the year ended December 31, 2004, decreasing sales of silicone IOLs were further intensified by the negative perception in the marketplace caused by the Warning Letters and recalls described below, resulting in a 14% decline in U.S. silicone IOL sales compared to fiscal 2003. The market s reaction to the compliance issues, along with an interruption in the supply of cartridges, also resulted in a decline in sales of Collamer IOLs. In contrast to recent periods in which improving sales of Collamer IOLs partially offset declining sales of silicone IOLs, sales of Collamer IOLs declined 8% in 2004 compared to fiscal 2003, worsening overall results for the U.S. cataract business and resulting in an overall decline of 7.8% in U.S. sales in 2004 compared to fiscal 2003.

Growth in International Sales of VISIAN ICLs and Preloaded Silicone IOLs. The decline in the U.S. cataract business during 2004 was offset in part by a 37.6% increase in international sales of the VISIAN ICL and TICL. In addition, our preloaded silicone lens injector system, newly launched in international markets, experienced strong sales. This growth in the business resulted in an increase in international sales of 11.5% in 2004 compared to 2003.

FDA Warning Letters and the 483 Observations. In 2004, we received Warning Letters and 483 Observations issued by the FDA, which outlined deficiencies related to our manufacturing and quality assurance systems in our Monrovia, California facility. For a discussion of the Warning Letters and 483

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Observations, see Business Regulatory Matters Warning Letters and the 483 Observations. Costs associated with the preparation for these FDA inspections, and the improvements made to the quality assurance and regulatory compliance functions, contributed to the 22% increase in our research and development expenses (which included regulatory and quality assurance expenses) for fiscal 2004, compared to fiscal 2003. Additionally, the Warning Letters and 483 Observations have affected the Company s reputation in the ophthalmic market and have adversely affected product sales for fiscal 2004. Until the FDA is satisfied with the Company s response, it is unlikely to grant the Company approval to market the ICL in the United States. See Risk Factors We have received 483 Inspectional Observations and Warning Letters from the FDA, which until resolved to the satisfaction of the FDA will continue to delay approval of the ICL and could limit our existing business in the United States. and Our success depends on the ICL, which has not been approved for use in the United States.

Foreign Currency Fluctuations. Our products are sold in more than 45 countries. For the year ended December 31, 2004, revenues from international operations were 58% of total revenues. The results of operations and the financial position of certain of our offshore operations are reported in the relevant local currencies and then translated into U.S. dollars at the applicable exchange rates for inclusion in our consolidated financial statements, exposing us to currency translation risk. For the year ended December 31, 2004, currency exchange rates had a favorable impact on product sales of approximately $2.2 million, and an adverse impact on our marketing and selling expenses of approximately $777,000.

Product Recalls. During 2004, we initiated several voluntary recalls of STAAR manufactured product including 33 lots of IOL cartridges, three lots of injectors, and 529 lenses. In an action considered a recall, but with no requirement for product to be returned to us, we issued letters to healthcare professionals advising them of the potential for a change in manifest refraction over time in rare cases involving the single-piece Collamer IOL. Although the direct costs associated with recalls have not been material, we believe recalls have adversely affected our revenues from product sales, although the amount of the impact cannot be determined.

Gross Profit. Our gross profit margin decreased to 50.6% in fiscal 2004 from 55.2% in fiscal 2003. Among the factors contributing to the decline in our gross profit margin were increased expenses associated with manufacturing engineering and quality control and assurance, an increase in inventory provisions, higher unit costs due to process changes and reduced volumes, and a shift in geographical and product mix.

Research and Development. We spent 12.1% of our revenue on research and development (which includes regulatory and quality assurance expenses) for the year ended December 31, 2004, and we expect to spend approximately 10% of our revenue on an annual basis in the future. For the year ended December 31, 2004, research and development expenses increased 22% compared to 2003. This was primarily due to our increased investment in injection systems, the redesign of the Collamer three-piece IOL and injector and preparation for the FDA audit of our facilities in Nidau, Switzerland and Monrovia, California, described above. Increases in research and development expense were partially offset by decreased expenses at subsidiaries, as all research and development efforts were consolidated into one location.

Private Placement. Due to the issues raised the FDA s Warning Letters and the delay in the FDA approval of the ICL, we sought additional cash to invest in research and development, regulatory and compliance, and manufacturing engineering and to support other operating activities. This was accomplished through the private placement of 4,100,000 shares of our Common Stock on April 4, 2005, which generated net proceeds of $13.5 million and 2,000,000 shares of our Common Stock on June 10, 2004 which generated net proceeds of $11.6 million.

Cash Flow. During fiscal 2004, we used $8.8 million in cash for operating activities and $1.7 million for property plant and equipment, ending fiscal 2004 with $9.3 million in cash and cash equivalents and short-term investments compared to $7.3 million in cash and cash equivalents at the end of fiscal 2003. We used $2.5 million in cash in the fourth quarter of 2004 and expect to use $3.5 million in the first quarter of 2005. During the fourth quarter of 2004, we took steps to reduce operating expenses by reducing our reliance on outside consultants. This reduction in spending is expected to result in savings of approximately $1.0 million annually. In early February 2005, we implemented additional cost reduction strategies, including the reduction

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in size of our direct sales force, which are expected to result in another $1.0 million in annualized cost savings. We will continue to pursue other cost savings opportunities with the goal of realizing a total of $3.0 million in annual cost savings. We do not expect to realize significant benefits from the cost reductions in the first quarter of 2005 and while the benefit of the cost reductions will be fully implemented in the second quarter, a continued decline in U.S. sales could offset some of the savings for future periods. The Company expects operating losses and negative cash flows to continue until such time as the issues presented in the FDA Warning Letter dated December 22, 2003 and the 483 Observations are resolved and the ICL is approved for sale in the United States.

Retention of Morgan Stanley. In December 2004, we engaged Morgan Stanley to assist our Board of Directors in a review of the strategic and financial options available to us.

Litigation. During 2004, multiple class action lawsuits, which were subsequently consolidated, were filed against the Company and its Chief Executive Officer on behalf of all persons who acquired the Company s securities during various periods between April 3, 2003 and September 28, 2004. See Item 3. Legal Proceedings.

Purchase of Minority Interest. In May 2004, we entered into an agreement for the purchase of the 20% minority interest of an 80% owned subsidiary, ConceptVision Australia Pty Limited, in exchange for cash of $768,000 and a long-term note in the amount of $542,000 due on November 1, 2007. The transaction resulted in the recording of goodwill of $1.1 million.

Results of Operations

The following table sets forth the percentage of total revenues represented by certain items reflected in the Company s income statement for the period indicated and the percentage increase or decrease in such items over the prior period.

	Percentage of Total Revenues			Percentage Change	
	December 31, 2004	January 2, 2004	January 3, 2003	2004 vs. 2003	2003 vs. 2002
Total revenues	100.0%	100.0%	100.0%	2.4%	(4.6)%
Cost of sales	49.4%	44.8%	49.9%	12.9%	(6.1)%
Gross profit	50.6%	55.2%	50.1%	(6.1)%	15.3%
Costs and expenses:					
General and administrative	17.9%	18.5%	18.6%	(1.0)%	4.3%
Marketing and selling	39.3%	38.7%	34.9%	4.1%	15.9%
Research and development	12.1%	10.1%	8.3%	22.0%	27.5%
Other charges	1.0%	0.8%	3.0%	28.2%	(73.2)%
Total costs and expenses	70.3%	68.1%	64.8%	5.6%	9.9%
Operating loss	(19.7)%	(12.9)%	(14.7)%	55.7%	(8.3)%
Other expense, net	(0.1)%	(1.3)%	(1.7)%	(86.2)%	(18.9)%
Loss before income taxes	(19.8)%	(14.2)%	(16.4)%	43.1%	(9.3)%
Income tax provision (benefit)	2.0%	2.2%	18.2%	(6.2)%	(87.2)%
Minority interest	0.1%	0.1%	0.2%	(57.4)%	(9.3)%
Net loss	(21.9)%	(16.5)%	(34.8)%	35.6%	(50.2)%

2004 Fiscal Year Compared to 2003 Fiscal Year

Revenues. Product sales for the years ended December 31, 2004 (fiscal 2004) and January 2, 2004 (fiscal 2003) were $51.7 million and $50.4 million, respectively. Changes in currency exchange rates had a favorable impact on product sales of approximately $2.2 million for fiscal 2004. The primary reason for the decrease in product sales, excluding the impact of exchange rates, was a decrease in U.S. IOL sales due to (i) the decline in the silicone IOL market as many surgeons now choose lenses made of acrylic material, (ii) the Company s failure to match competitors

improvements to IOL technology, (iii) the market response to the Company s compliance issues with the FDA and (iv) the lack of competitive lens delivery systems. The

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Company also experienced decreased sales of distributed products as it concentrates on the distribution of its higher margin proprietary products. The decreases in U.S. IOL sales and sales of distributed products were partially offset by increased sales of the Company s Visian™ ICL (ICL) and Visian™ TICL (TICL) in international markets, sales of the newly launched preloaded IOLs in international markets, and increased sales of Cruise Control.

Total revenues for 2003 included $49,000 in royalties from technology licenses that terminated in 2003.

Gross profit. Gross profit margin decreased to 50.6% of revenues for fiscal 2004, from 55.2% of revenues for fiscal 2003. The most significant impact on gross margins resulted from increased expenses associated with manufacturing engineering and quality control and assurance, an increase in inventory provisions, higher unit costs due to process changes and reduced volumes, and a shift in geographical and product mix.

Marketing and selling expenses. Marketing and selling expenses for fiscal 2004 increased $793,000, or 4%, over fiscal 2003. The increase is principally due to fluctuations in foreign exchange rates which negatively impacted marketing and selling expenses by $777,000. International sales and marketing expenses increased due to increased salaries, travel, and commissions. Headcount in the U.S. increased due to the addition of direct sales representatives for a newly established sales territory in the Pacific Northwest Region and as a result of the addition of proctors-trainers used principally to train physicians in the ICL implantation technique. These increases were offset by decreased promotional activities, primarily in response to the delay in the launch of the Visian™ ICL in the U.S. and the cost savings realized from the closure of a subsidiary.

Research and development expenses. Research and development expenses for the fiscal 2004, increased $1,127,000, or 22%, compared to fiscal 2003. This was primarily due to our increased investment in insertion systems, the redesign of the Collamer three-piece IOL and injector and preparation for the FDA audit of our facilities in Nidau, Switzerland and Monrovia, California. Increases in research and development expense were partially offset by decreased research and development expenses of subsidiaries, as all research and development efforts were consolidated into one location.

Other charges. Other charges for fiscal 2004 were $500,000 compared to $390,000 in fiscal 2003. During fiscal 2004, the Company recorded a $500,000 reserve against the notes of a former director of the Company which total $1.8 million including accrued interest. The notes are collateralized by 120,000 shares of the Company s Common Stock and a second mortgage on a home in Florida. The current value of the collateral is approximately $1.3 million. The amount of the reserve is based on the difference between the note amount and the collateral value.

Other expense, net. Other expense for fiscal 2004 decreased $549,000 over fiscal 2003. Included in other expense for fiscal 2003 was the write-off of a note receivable in the amount of $430,000. During fiscal 2004, the Company recovered $200,000 of the note and recorded the cash received as other income. These increases in other income were partially offset by losses recorded in 2004 by the Company s joint venture, Canon Staar.

Income taxes. For each of fiscal 2004 and fiscal 2003, the Company recorded income taxes of $1.1 million primarily based on the income of the Company s German subsidiary.

In 1995, a subsidiary of the Company obtained retroactively to 1993, a ten-year tax holiday for the payment of federal, cantonal and municipal income taxes in Switzerland. As such, Swiss income taxes were not due on the operations of this subsidiary for the ten-year period that ended on December 31, 2002. For 2004 and 2003, as the tax holiday from Swiss taxes has expired, the appropriate federal, cantonal and municipal income taxes have been included in the foreign tax provision.

Negotiations to extend the Swiss tax holiday are ongoing. The Swiss tax authorities are considering granting an extension of the tax holiday with respect to new products including the ICL, the Toric ICL and the AquaFlow Device. If the tax holiday is extended, it will likely be applied prospectively.

2003 Fiscal Year Compared to 2002 Fiscal Year

Revenues. Revenues for fiscal 2003 increased over the year ended January 3, 2003 (fiscal 2002) by 4.6% or $2,210,000 due to the favorable impact of foreign exchange on sales of other ophthalmic products

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distributed in international markets. Excluding the favorable impact of foreign exchange, sales decreased 2%. The decrease in sales is due primarily to a decrease in unit volume of the Company s single and three-piece silicone IOL, primarily in the U.S. market, due to a decline in competitiveness of the Company s lens delivery systems and believed contraction of this market segment. The decrease in sales of silicone IOLs was partially offset by increased sales in the U.S. of Collamer IOLs (28% increase in volume partially offset by a 6% decrease in average selling price ASP). As a result of the decreased silicone IOL sales in the U.S., overall sales in that market declined 3%. Sales of the AquaFlow Device decreased 19% (15% decrease in volume and a 5% decrease in ASP) over 2002. This sales decrease was also realized in the U.S. and was the result of sales and marketing resources which have been diverted from AquaFlow proctoring and training to surgical evaluations of silicone lens injection systems and preparation for possible FDA approval of the ICL.

The decreases in single and three-piece silicone IOL and AquaFlow sales were further offset by increased sales of ICLs, Toric IOLs, STAARVisc, and Cruise Control. Sales of ICLs in international markets increased 31% due to a 26% increase in units and a 4% increase in ASP. Sales of STAARVisc increased 17% on a 25% increase in volume partially offset by a 7% decrease in ASP. Sales of Toric IOLs increased 3% due to a 10% increase in volume partially offset by a 6% decline in ASP. Sales in international markets decreased 2% (excluding the impact of exchange) due to a decrease in equipment sales in Australia.

Gross profit. Gross profit for fiscal 2003 was 55.2% of revenues compared to fiscal 2002 when it was 50.1% of revenues. The improvement in gross profit margin is the result of successfully increasing standard margins across all of our primary product lines through reduced cost structures resulting from better yields, efficiencies and volume, and reducing other costs of sales through better management of excess and obsolete inventories. Additionally, the Company streamlined its phacoemulsification manufacturing and repair division, during the year, resulting in lower costs and improved gross profit for this product line.

Marketing and selling expenses. Marketing and selling expenses for fiscal 2003 increased $2.7 million, or 16%, over fiscal 2002. Marketing and selling expense in the U.S. increased by $1.7 million as a result of marketing and promotional costs which increased, as planned, in preparation for the launch of the ICL and increased headcount and associated recruiting costs in preparation for launch of the ICL in the U.S., the addition of direct sales representatives for a newly established Pacific Northwest Region, increased travel expenses and increased salaries. Marketing and selling expense increased internationally by $1.0 million primarily due to the unfavorable impact of exchange rates partially offset by reduced expenses of subsidiaries which were closed in 2002 and 2003.

Other charges. Other charges for fiscal 2003 were $390,000 compared to fiscal 2002 when they were $1.5 million. The charges in 2003 related to the write-down of $2.1 million (net book value) in capitalized patent costs in connection with the Company s routine evaluation of such costs in accordance with Statement of Financial Accounting Standards No. 144 (SFAS 144) Accounting for the Impairment of Long-Lived Assets. The write-down related to patents acquired in 1999 in the purchase of the Company s majority interest in Circuit Tree Medical, a developer and manufacturer of phacoemulsification equipment, whose ongoing operations were moved to the Company s Monrovia, California facility. The $2.1 million charge was partially offset by the reversal of $1.7 million of reserves against former officers notes which were paid during the year.

Other expense, net. Other expense for fiscal 2003 decreased $148,000 over fiscal 2002. The decreased expense is due to decreased interest expense and foreign exchange losses partially offset by decreased interest income from officers notes that were paid in full and a $430,000 reserve on a note receivable the Company recorded during the year.

Income taxes. Income taxes for fiscal 2003 decreased $7.7 million over the fiscal 2002. The high provision for income taxes in 2002 was the result of a valuation allowance of $9.0 million recorded against the Company s deferred tax assets, partially offset by an income tax benefit of approximately $1.0 million related to a federal carryback claim filed in 2002. The tax refund from the carryback claim was received in 2003.

In 1995, a subsidiary of the Company obtained retroactively to 1993, a ten-year tax holiday for the payment of federal, cantonal and municipal income taxes in Switzerland. As such, Swiss income taxes were

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not due on the operations of this subsidiary for the ten-year period that ended on December 31, 2002. For 2003, as the tax holiday from Swiss taxes has expired, the appropriate federal, cantonal and municipal income taxes have been included in the foreign tax provision.

Negotiations to extend the Swiss tax holiday are ongoing. The Swiss tax authorities are considering granting an extension of the tax holiday with respect to new products including the ICL, the Toric ICL and the AquaFlow Device. If the tax holiday is extended, it will likely be applied prospectively.

Liquidity and Capital Resources

The Company has funded its activities over the past several years principally from cash flow generated from operations, credit facilities provided by institutional domestic and foreign lenders, the private placement of Common Stock, the repayment of former officers notes, and the exercise of stock options.

Net cash provided by (used in) operating activities was ($8.8) million, ($4.1) million, and $0.6 million for fiscal 2004, 2003, and 2002, respectively. For fiscal 2004, cash used in operations was the result of the net loss, adjusted for depreciation, amortization, and other non-cash charges, and increases in working capital primarily accounts receivable, inventory, accounts payable and other current liabilities. For fiscal 2003, cash used in operations was the result of the net loss, adjusted for depreciation, amortization, the write-off of patents, and other non-cash charges. For fiscal 2002, cash provided by operations was the result of the net loss, adjusted for depreciation, amortization, deferred income taxes, and other non-cash charges, and decreases in working capital primarily accounts receivable, inventory, and accounts payable.

Accounts receivable was $6.2 million in 2004, $5.7 million in 2003, and $6.0 million in 2002. The increase in accounts receivable is due to increased sales, the write-off of a receivable, reserved in the previous year, of a distributor that discontinued its operations and a slight increase in day s sales outstanding (DSO). Although DSO improved from 45 days in 2002 to 39 days in 2003 it increased slightly, as expected, to 41 days in 2004. The Company expects DSO to continue in the 40-43 day range for 2005.

Inventory at year-end 2004, 2003, and 2002 was $15.1 million, $12.8 million, and $11.8 million, respectively. Day s inventory on hand increased from 176 days in 2002 to 204 days in 2003, and decreased to 186 days in 2004. Although inventory units have decreased overall from 2003 to 2004, the decrease was more than offset by higher cost inventory that was produced during the year as a result of lower than planned production volume resulting in an increase in inventory of $2.3 million in 2004 over 2003. Inventory, at the end of 2003, increased $1.0 million over 2002 levels due to the build-up of ICL inventory in preparation of the launch of the product in the U.S. and increased collamer IOL inventory based on increased demand for the product. High cost inventory, built in 2001, was sold during 2002 and replaced with lower cost inventory resulting in an overall decrease in inventory at the end of 2002 of $3.5 million over 2001.

Net cash provided by (used in) investing activities was approximately ($7,294,000), $2,151,000, and ($406,000) for fiscal 2004, 2003, and 2002, respectively. During 2004, the Company invested $8.0 million of the proceeds of a private placement in taxable auction-rate securities which are classified as available for sale investments and sold $2.9 million of the investment during the year to provide cash for operations. Also during 2004, the Company purchased the 20% minority interest in an 80% owned subsidiary in exchange for cash of $768,000 and a long-term note in the amount of $542,000 due on November 1, 2007. The transaction resulted in the recording of goodwill of $1.1 million. Proceeds from the payment of notes of former officers were the primary source of cash provided by investing activities in 2003. The principal investments of the Company are in property and equipment. Investments in property and equipment were $1.7 million, $1.3 million, and $874,000 for fiscal 2004, 2003, and 2002, respectively. The investments are generally made to upgrade and improve existing production equipment and processes. The Company expects to spend approximately $1.0 million on property and equipment in 2005.

Net cash provided by (used in) financing activities were approximately $12,547,000, $7,589,000, and ($592,000) for fiscal 2004, 2003, and 2002, respectively. In 2004, cash provided by financing activities resulted from the receipt of net proceeds of $11.6 million from a private placement of 2.0 million shares of the Company s Common Stock and $829,000 received from the exercise of stock options. In 2003, cash provided

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by financing activities is primarily the result of net proceeds of $8.9 million from a private placement of the Company s Common Stock and $1.6 million received from the exercise of stock options. The Company used approximately $2.1 million of the proceeds to pay off the note to its domestic lender and $812,000 to pay down other notes payable. In 2002, the Company used $592,000 in cash to pay down notes payable.

Subsidiaries of the Company have foreign credit facilities with different banks to support operations in Switzerland and Germany.

The Swiss credit agreement, as amended on August 2, 2004, provides for borrowings of up to 3.75 million Swiss Francs CHF (approximately $3.3 million based on the rate of exchange on December 31, 2004), and permits either fixed-term or current advances. The interest rate on current advances was 6.0% per annum at both December 31, 2004 and January 2, 2004, plus a commission rate of 0.25% payable quarterly. There were no current advances outstanding at December 31, 2004 or January 2, 2004. The base interest rate for fixed-term advances follows Euromarket conditions for loans of a corresponding term and currency, plus an individual margin (4.5% at December 31, 2004 and 4.2% at January 2, 2004). Borrowings outstanding under the facility were CHF 3.4 million at December 31, 2004 (approximately $3.0 million based on the rate of exchange at December 31, 2004) and CHF 3.7 million at January 2, 2004 (approximately $3.0 million based on the rate of exchange on January 2, 2004). The credit facility is secured by a general assignment of claims and includes positive and negative covenants which, among other things, require the maintenance of a minimum level of equity of at least $12.0 million and prevents the Swiss subsidiary from entering into other secured obligations or guaranteeing the obligations of others. The agreement also prohibits the sale or transfer of patents or licenses without the prior consent of the lender and the terms of intercompany receivables may not exceed 90 days.

The Swiss credit facility is divided into two parts. Part A provides for borrowings of up to CHF 3.0 million ($2.7 million based on the exchange rate on December 31, 2004) and does not have a termination date. Part B presently provides for borrowings of up to CHF 750,000 ($662,000 based on the exchange rate on December 31, 2004). The loan amount under Part B of the agreement is reduced by CHF 250,000 ($220,000 based on the exchange rate on December 31, 2004) semi-annually.

The German credit agreement, entered into during fiscal 2003, provides for borrowings of up to 210,000 EUR ($286,000 based on the exchange rate on December 31, 2004), at a rate of 8.5% per annum and renews automatically each November. The agreement prohibits our German subsidiary from paying dividends and is personally guaranteed by the president of the subsidiary. There were no borrowings outstanding as of December 31, 2004 or January 2, 2004.

The Company was in compliance with the covenants of these credit facilities as of December 31, 2004.

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The following table represents the Company s known contractual obligations included in the Company s balance sheet as of December 31, 2004.

	Payments Due by Period				
Contractual Obligations	**Total**	**Less Than 1 Year**	**1-3 Years**	**3-5 Years**	**More Than 5 Years**
			(In thousands)		
Notes payable	$ 3,004	$ 3,004	$	$	$
Capital lease obligations	105	92	11	2	
Operating lease obligations	2,286	927	1,307	52	
Purchase obligations	1,222	1,022	200		
Open purchase orders	1,212	1,212			
Other long-term liabilities	542		542		
Total	$ 8,371	$ 6,257	$ 2,060	$ 54	$

The table presented above excludes the following information: (a) interest due on notes payable under the Swiss credit agreement and (b) employment agreements for the two previous minority owners of our Australian subsidiary. See Note 9 to the Consolidated Financial Statements.

Due to a continued decline in U.S. sales, lower gross profit, and increased operating expenses the Company sustained significant losses and negative cash flows from operations for the year ended December 31, 2004. In order to fund its current operations including its research and development and regulatory and compliance efforts, the Company has relied on cash provided by private placements of its Common Stock, which generated net proceeds of $13.5 million on April 4, 2005 and $11.6 million on June 10, 2004. The Company believes that as a result of these financings, it currently has sufficient cash to meet its funding requirements over the next year. However, the Company expects operating losses and negative cash flows to continue until such time as the issues presented in the FDA Warning Letter dated December 22, 2003 and the 483 Observations are resolved and the ICL is approved for sale in the U.S. To reduce operating losses and negative cash flows for the year ended December 30, 2005, the Company expects to take the following actions: (1) continue to aggressively address the issues presented in the FDA Warning Letter of December 22, 2003 and the 483 Observations; (2) work closely with the independent sales force and ophthalmic community to reverse the negative perceptions and sales trends of the Company s existing lines of business; (3) further reduce discretionary spending; and (4) explore other strategic and financial options. However, there can be no assurance that the Company will be successful in executing its strategies.

The Company s liquidity requirements arise from the funding of its working capital needs, primarily inventory, work-in-process and accounts receivable. The Company s primary sources for working capital and capital expenditures are cash flow from operations, proceeds from the private placement of Common Stock, proceeds from option exercises, debt repayments by former officers, and borrowings under the Company s foreign bank credit facilities. Any withdrawal of support from its banks could have serious consequences on the Company s liquidity. The Company s liquidity is dependent, in part, on customers paying within credit terms, and any extended delays in payments or changes in credit terms given to major customers may have an impact on the Company s cash flow. In addition, any abnormal product returns or pricing adjustments may also affect the Company s short-term funding.

The business of the Company is subject to numerous risks and uncertainties that are beyond its control, including, but not limited to, those set forth above and in the other reports filed by the Company with the Securities and Exchange Commission. Such risks and uncertainties could have a material adverse effect on the Company s business, financial condition, operating results and cash flows. See Risk Factors.

Critical Accounting Policies

The preparation of financial statements in accordance with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the

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reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. On an on-going basis, we evaluate our estimates, including those related to revenue recognition, allowance for doubtful accounts, inventory reserves and income taxes, among others. Our estimates are based upon historical experiences, market trends and financial forecasts and projections, and upon various other assumptions that management believes to be reasonable under the circumstances and at that certain point in time. Actual results may differ, significantly at times, from these estimates under different assumptions or conditions.

The Company believes the following represent its critical accounting policies.

Revenue Recognition and Accounts Receivable. The Company recognizes revenue when realized or realizable and earned, which is when the following criteria are met: persuasive evidence of an arrangement exists; delivery has occurred; the sale price is fixed and determinable; and collectibility is reasonably assured. We record revenue from product sales when title and risk of ownership has been transferred to the customer, which is typically upon delivery to the customer. The exception to this recognition policy is revenue from IOLs distributed on a consignment basis, which is recognized upon notification of implantation in a patient.

The Company may bundle the sale of phacoemulsification equipment to customers with multi-year agreements to purchase minimum quantities of foldable IOLs. The Company recognizes the revenue from the equipment based on monthly purchases of minimum quantities of IOLs over the life of the agreement.

Revenue from license and technology agreements is recorded as income, when earned, according to the terms of the respective agreements.

The Company generally permits returns of product if such product is returned within the time allowed by the Company, and in good condition. Allowances for returns are provided for based upon an analysis of our historical patterns of returns matched against the sales from which they originated. To date, historical product returns have been within the Company s estimates.

The Company maintains provisions for uncollectible accounts for estimated losses resulting from the inability of its customers to remit payments. The Company continuously monitors collections and payments from its customers and maintains a provision for estimated credit losses based upon its historical experience and any specific customer collection issues that have been identified.

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

Income Taxes. We account for income taxes under the asset and liability method, whereby deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. We evaluate the need to establish a valuation allowance for deferred tax assets based upon the amount of existing temporary differences, the period in which they are expected to be recovered and expected levels of taxable income. A valuation allowance to reduce deferred tax assets is established when it is more likely than not that some or all of the deferred tax assets will not be realized. As of the years ended December 31, 2004 and January 2, 2004, the valuation allowance fully

offsets the value of deferred tax assets on the Company s balance sheet.

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We expect to continue to maintain a full valuation allowance on future tax benefits until an appropriate level of profitability is sustained, or we are able to develop tax strategies that would enable us to conclude that it is more likely than not that a portion of our deferred tax assets would be realizable.

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

Impairment of Long-Lived Assets. Intangible and other long lived-assets are reviewed for impairment whenever events such as product discontinuance, plant closures, product dispositions or other changes in circumstances indicate that the carrying amount may not be recoverable. In reviewing for impairment, the Company compares the carrying value of such assets to the estimated undiscounted future cash flows expected from the use of the assets and their eventual disposition. When the estimated undiscounted future cash flows are less than their carrying amount, an impairment loss is recognized equal to the difference between the assets fair value and their carrying value.

Goodwill. Goodwill, which has an indefinite life and was previously amortized on a straight-line basis over the periods benefited, is no longer amortized to earnings, but instead is subject to periodic testing for impairment. Intangible assets determined to have definite lives are amortized over their remaining useful lives. Goodwill of a reporting unit is tested for impairment on an annual basis or between annual tests if an event occurs or circumstances change that would reduce the fair value of a reporting unit below its carrying amount. As provided under SFAS No. 142, an annual assessment was completed during 2004, and no impairment was identified. As of December 31, 2004, the carrying value of goodwill was $7.5 million.

Patents and Licenses. The Company also has other intangible assets consisting of patents and licenses, with a gross book value of $11.5 million and accumulated amortization of $6.1 million as of December 31, 2004. Amortization is computed on the straight-line basis over the estimated useful lives, which are based on legal and contractual provisions, and range from 10 to 20 years.

Risk Factors

Our short and long-term success is subject to many factors that are beyond our control. Stockholders and prospective stockholders in the Company should consider carefully the following risk factors, in addition to other information contained in this report. This Annual Report on Form l0-K contains forward-looking statements, which are subject to a variety of risks and uncertainties. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth below.

Risks Related to Our Business

We have a history of losses and anticipate future losses.

We have reported losses in each of the last three fiscal years and have an accumulated deficit of $60.5 million as of December 31, 2004. There can be no assurance that we will report net income in any future period.

We have only limited working capital.

Our current sources of working capital are sufficient to satisfy our anticipated working capital requirements for fiscal 2005. However, the issues resulting from the Warning Letter of December 22, 2003 and the 483 Observations raise uncertainties about the sufficiency of our working capital for future years and we may have to consider alternative sources of funding. There can be no assurance as to the availability of such funding or the terms upon which it might be available.

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We have limited access to credit and could default on the terms of our loan agreement.

As of December 31, 2004, we have outstanding balances on the credit facility of a European subsidiary of approximately $3.0 million, based on exchange rates on that date. If our losses continue, we risk defaulting on the terms of our credit facility, particularly as it relates to the maintenance of minimum levels of equity and the payment of intercompany receivables.

We have only limited access to financing.

Because of our history of losses, we may not be able to obtain future financing on satisfactory terms or at all. Any such financing may involve substantial dilution to existing shareholders.

We have received 483 Inspectional Observations and Warning Letters from the FDA, which until resolved to the satisfaction of the FDA will continue to delay approval of the ICL and could limit our existing business in the United States.

On December 29, 2003 and April 26, 2004, we received Warning Letters issued by the FDA. A copy of the first Warning Letter is attached as Exhibit 99.1 to our Current Report on Form 8-K filed with the Securities and Exchange Commission on January 9, 2004, and a copy of the second Warning Letter is attached as Exhibit 99.1 to our Current Report on Form 8-K filed with the Securities and Exchange Commission on May 6, 2004.

On September 23, 2004, the FDA completed a re-audit of our Monrovia, California manufacturing facility. At the conclusion of the audit, the FDA issued a form FDA 483 Inspectional Observations described more fully in our Current Report on Form 8-K filed with the Securities and Exchange Commission on September 29, 2004.

The Warning Letters and 483 Observations have adversely affected our reputation in the ophthalmic industry and our product sales. Until the FDA is satisfied with our response, it is unlikely to grant us approval to market the ICL and the TICL in the United States and may place restrictions on our domestic lines of business. See Business Regulatory Matters Warning Letters and the 483 Observations.

Our success depends on the ICL, which has not been approved for use in the United States.

We have devoted significant resources and management attention to the development and introduction of our ICL and TICL. Management believes that the future success of STAAR depends on the approval of the ICL for sale in the United States by the FDA. The ICL is already approved for use in the European Union and Canada and in parts of Asia. The TICL is approved for use in the European Union. In October 2003, the FDA Ophthalmic Devices Panel recommended that the FDA approve, with conditions, specified uses of the ICL. The FDA has not yet acted on this recommendation, and it could decide to reject the Ophthalmic Devices Panel recommendations. Until the FDA is satisfied with our response to its Warning Letter dated December 22, 2003 and its 483 Observations issued on September 23, 2004, it is unlikely to grant us approval to market the ICL and the TICL in the United States. If the FDA does not grant approval of the ICL, or significantly delays its approval, whether because of the issues contained in the Warning Letter, the 483 Observations or otherwise, our prospects for success will be severely diminished.

Our future success depends on the successful marketing of the ICL in the United States market.

Even if it is approved by the FDA for sale in the United States, the ICL will not reach its full sales potential unless we successfully plan and execute its launch and marketing in the United States. This will present new challenges to our sales and marketing staff and to our independent manufacturers representatives. In countries where the ICL has been approved to date, our sales have grown steadily, but slowly. In the United States in particular, patients who might benefit from the ICL have already been exposed to a great deal of advertising and publicity about laser refractive surgery, but have little if any awareness of the ICL. As a result, we expect to make extensive use of advertising and promotion targeted to potential patients through providers, and to carefully manage the introduction of the ICL. We do not have significant resources and we cannot

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predict whether the particular marketing, advertising and promotion strategies we pursue will be as successful as we intend. If we do not successfully market the ICL in the United States, we will not achieve our planned profitability and growth.

Our core domestic business has suffered declining sales, which sales of new products have only partially offset.

STAAR pioneered the foldable IOL for use in cataract surgery, and the foldable silicone IOL is one of our largest sources of revenue. Since we introduced the product, however, competitors have introduced IOLs employing a variety of designs and materials. Over the years these products have gradually taken a larger share of the IOL market, while the market share for our IOLs has decreased. In particular, many surgeons now choose lenses made of acrylic material rather than silicone for their typical patients. In an effort to maintain our competitive position we have introduced a new biocompatible lens material, Collamer, to our line of IOLs. We have also introduced new IOL designs, such as the Toric IOL, and have continued to improve and refine the silicone IOL. Sales of these new products, however, have only partially offset declining sales of our silicone IOLs.

We depend on independent manufacturers representatives.

In an effort to manage costs and bring our products to a wider market, we have entered into long-term agreements with certain independent regional manufacturers representatives, who introduce our products to eye surgeons and provide the training needed to begin using some of our products. Under our agreements with these representatives, each receives a commission on all of our sales within a specified region, including sales on products we sell into their territories without their assistance. Because they are independent contractors, we have a limited ability to manage these representatives or their employees. In addition, a representative may represent manufacturers other than STAAR, although not in competing products. We have been relying on the independent representatives to introduce our new products like Collamer IOLs, Toric IOLs and the AquaFlow Device, and we will rely on them, in part, to help introduce the ICL if it is approved. If our independent manufacturers representatives do not devote sufficient resources to marketing our products, or if they lack the skills or resources to market our new products, our new products will fail to reach their full sales potential and sales of our established products could decline.

Product recalls have been costly and may be so in the future.

Medical devices must be manufactured to the highest standards and tolerances, and often incorporate newly developed technology. Despite all efforts to achieve the highest level of quality control and advance testing, from time to time defects or technical flaws in our products may not come to light until after the products are sold or consigned. In those circumstances, we have previously made voluntary recalls of our products. During 2004, we initiated several voluntary recalls of STAAR manufactured product including 33 lots of IOL cartridges, three lots of injectors, and 529 lenses, and in February 2004, in an action considered a recall but with no requirement for product to be returned to us, we issued a letter to healthcare professionals advising them of the potential for a change in manifest refraction over time in rare cases involving the single-piece Collamer IOL. Similar recalls could take place again. Courts or regulators can also impose mandatory recalls on us, even if we believe our products are safe and effective. Recalls can result in lost sales of the recalled products themselves, and can result in further lost sales while replacement products are manufactured, especially if the replacements must be redesigned. If recalled products have already been implanted, we may bear some or all of the cost of corrective surgery. Recalls may also damage our professional reputation and the reputation of our products. The inconvenience caused by recalls and related interruptions in supply, and the damage to our reputation, could cause some professionals to discontinue using our products.

We could experience losses due to product liability claims.

We have in the past been, and continue to be, subject to product liability claims. As part of our risk management policy, we have obtained third-party product liability insurance coverage. Product liability claims against us may exceed the coverage limits of our insurance policies or cause us to record a self-insured loss. A

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

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

We compete with much larger companies.

Our competitors, including Alcon, Advanced Medical Optics, and Bausch & Lomb, have much greater financial resources than we do and some of them have large international markets for a full suite of ophthalmic products. Their greater resources for research, development and marketing, and their greater capacity to offer comprehensive products and equipment to providers, make it difficult for us to compete. We have lost significant market share to some of our competitors.

Most of our products have single-site manufacturing approvals, exposing us to risks of business interruption.

We manufacture all of our products either at one of our facilities in California or at our facility in Switzerland. Most of our products are approved for manufacturing only at one of these sites. Before we can use a second manufacturing site for an implantable device we must obtain the approval of regulatory authorities. Because this process is expensive we have generally not sought approvals needed to manufacture at an additional site. If a natural disaster, fire, or other serious business interruption struck one of our manufacturing facilities, it could take a significant amount of time to validate a second site and replace lost product. We could lose customers to competitors, thereby reducing sales, profitability and market share.

The global nature of our business may result in fluctuations and declines in our sales and profits.

Our products are sold in more than 45 countries. Revenues from international operations make up a significant portion of our total revenue. For the year ended December 31, 2004 revenues from international operations were 58% of total revenues. The results of operations and the financial position of certain of our offshore operations are reported in the relevant local currencies and then translated into United States dollars at the applicable exchange rates for inclusion in our consolidated financial statements, exposing us to translation risk. In addition, we are exposed to transaction risk because some of our expenses are incurred in a different currency from the currency in which our revenues are received. Our most significant currency exposures are to the Euro, the Swiss Franc, and the Australian dollar. The exchange rates between these and other local currencies and the United States dollar may fluctuate substantially. We have not attempted to offset our exposure to these risks by investing in derivatives or engaging in other hedging transactions. Fluctuations in the value of the United States dollar against other currencies have not had a material adverse effect on our operating margins and profitability in the past.

Economic, social and political conditions, laws, practices and local customs vary widely among the countries in which we sell our products. Our operations outside of the United States are subject to a number of risks and potential costs, including lower profit margins, less stringent protection of intellectual property and economic, political and social uncertainty in some countries, especially in emerging markets. Our continued success as a global company depends, in part, on our ability to develop and implement policies and strategies that are effective in anticipating and managing these and other risks in the countries where we do business. These and other risks may have a material adverse effect on our operations in any particular country and on our business as a whole. We price some of our products in U.S. dollars, and as a result changes in exchange rates can make our products more expensive in some offshore markets and reduce our revenues. Inflation in

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emerging markets also makes our products more expensive there and increases the credit risks to which we are exposed.

We obtain some of the components of our products from a single source, and an interruption in the supply of those components could reduce our revenue.

We obtain some of the components for our products from a single source. For example, only one supplier produces our viscoelastic product. Although we believe we could find alternate supplies for any of these components, the loss or interruption of any of these suppliers could increase costs, reducing our revenue and profitability, or harm our customer relations by delaying product deliveries.

Our activities involve hazardous materials and emissions and may subject us to environmental liability.

Our manufacturing, research and development practices involve the controlled use of hazardous materials. We are subject to federal, state, local and foreign laws and regulations in the various jurisdictions in which we have operations governing the use, manufacturing, storage, handling and disposal of these materials and certain waste products. Although we believe that our safety and environmental procedures for handling and disposing of these materials comply with legally prescribed standards, we cannot completely eliminate the risk of accidental contamination or injury from these materials. Remedial environmental actions could require us to incur substantial unexpected costs, which would materially and adversely affect our results of operations. If we were involved in a major environmental accident or found to be in substantial non-compliance with applicable environmental laws, we could be held liable for damages or penalized with fines.

We risk losses through litigation.

Since September 1, 2004, multiple class action lawsuits have been filed in the United States District Courts for the Central District of California and the District of New Mexico against the Company and its Chief Executive Officer on behalf of all persons who acquired the Company s securities during various periods between April 3, 2003 and September 28, 2004. On December 15, 2004, the Court ordered consolidation of the complaints that had been filed in the United States District Court for the Central District of California and directed that the plaintiffs file a consolidated complaint as soon as practicable. The plaintiffs have proposed a stipulation pursuant to which they would file a consolidated amended complaint on or about April 29, 2005. The New Mexico action was voluntarily dismissed on January 28, 2005. The lawsuits generally allege that the defendants violated Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, as amended, and Rule 10b-5 promulgated thereunder, by issuing false and misleading statements regarding intraocular lenses and implantable lenses, and failing timely to disclose significant problems with the lenses, as well as the existence of serious injuries and/or malfunctions attributable to the lenses, thereby artificially inflating the price of the Company s Common Stock. The plaintiffs generally seek to recover compensatory damages, including interest. While we intend to vigorously defend the consolidated lawsuit, the lawsuit will require significant attention of management and could result in substantial costs and harm our reputation.

We are currently party to various claims and legal proceedings arising out of the normal course of our business. These claims and legal proceedings relate to contractual rights and obligations, employment matters, and claims of product liability. While we do not believe that any of the claims known to us is likely to have a material adverse effect on our financial condition or results of operations, new claims or unexpected results of existing claims could lead to significant financial harm.

We depend on key employees.

We depend on the continued service of our senior management and other key employees. The loss of a key employee could hurt our business. We could be particularly hurt if any key employee or employees went to work for competitors. Our future success depends on our ability to identify, attract, train and motivate other highly skilled personnel. Failure to do so may adversely affect future results.

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We have licensed our technology to our joint venture company and have granted certain rights to the partners that could be exercised in the event of a change in control of the Company.

We have granted to the Canon Staar joint venture, a perpetual exclusive license under the Licensed Technology (as defined in the license agreement) to make and sell our products in Japan, and to make our products in China and to sell such products in Japan and China. In addition, we have granted Canon Staar a perpetual non-exclusive license under the Licensed Technology to make and sell our products in the rest of the world. Subject to the approval of the Board of Directors of the joint venture, such licenses may allow the Canon Staar joint venture to sell products in the rest of the world or grant others the right to do so. The term Licensed Technology includes any intellectual property owned or controlled by STAAR.

Upon the occurrence of certain events, including the merger, sale of substantially all of the assets or change in the management of any party to the Canon Staar joint venture, any joint venture partner may have the right to acquire the first party s interest in the joint venture at book value, without terminating the licenses under the Licensed Technology.

The joint venture agreement, license agreement and settlement agreement relating to Canon Staar have been filed or incorporated by reference to this Annual Report.

Risks Related to the Ophthalmic Products Industry

If we fail to keep pace with advances in our industry or fail to persuade physicians to adopt the new products we introduce, customers may not buy our products and our revenue may decline.

Constant development of new technologies and techniques, frequent new product introductions and strong price competition characterize the ophthalmic industry. The first company to introduce a new product or technique to market usually gains a significant competitive advantage. Our future growth depends, in part, on our ability to develop products to treat diseases and disorders of the eye that are more effective, safer, or incorporate emerging technologies better than our competitors products. Sales of our existing products may decline rapidly if one of our competitors introduces a substantially superior product, or if we announce a new product of our own. Similarly, if we fail to make sufficient investments in research and development or if we focus on technologies that do not lead to better products, our current and planned products could be surpassed by more effective or advanced products.

In addition, we must manufacture these products economically and market them successfully by persuading a sufficient number of eye care professionals to use them. For example, glaucoma requires ongoing treatment over a long period of time; thus, many doctors are reluctant to switch a patient to a new treatment if the patient s current treatment for glaucoma remains effective. This has been a challenge in selling our AquaFlow Device.

Resources devoted to research and development may not yield new products that achieve commercial success.

We spent 12.1% of our revenue on research and development (including regulatory and quality assurance expenses) for the year ended December 31, 2004, and we expect to spend between 10-11% of our revenue on an annual basis in the future. Development of new implantable technology, from discovery through testing and registration to initial product launch, is expensive and typically takes from three to seven years. Because of the complexities and uncertainties of ophthalmic research and development, products we are currently developing may not complete the development process or obtain the regulatory approvals required for us to market the products successfully. It is possible that few or none of the products currently under development will become commercially successful.

Failure of users of our products to obtain adequate reimbursement from third-party payors could limit market acceptance of our products, which could affect our sales and profits.

Many of our products, in particular IOLs and products related to the treatment of glaucoma, are used in procedures that are typically covered by health insurance, HMO plans, Medicare or Medicaid. These third-

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party payors have recently been trying to contain costs by restricting the types of procedures they reimburse to those viewed as most cost-effective and capping or reducing reimbursement rates. These policies could adversely affect sales and prices of our products. Physicians, hospitals and other health care providers may be reluctant to purchase our products if third-party payors do not adequately reimburse them for the cost of our products and the use of our surgical equipment. For example:

Major third-party payors for hospital services, including government insurance plans, Medicare, Medicaid and private health care insurers, have substantially revised their payment methodologies during the last few years, resulting in stricter standards for reimbursement of hospital and outpatient charges for some medical procedures, including cataract procedures and IOLs;

Numerous legislative proposals have been considered that, if enacted, would result in major reforms in the United States health care system, which could have an adverse effect on our business;

Our competitors may reduce the prices of their products, which could result in third-party payors favoring our competitors;

There are proposed and existing laws and regulations governing maximum product prices and the profitability of companies in the health care industry; and

There have been recent initiatives by third-party payors to challenge the prices charged for medical products. Reductions in the prices for our products in response to these trends could reduce our revenues. Moreover, our products may not be covered in the future by third-party payors, which would also reduce our revenues.

We are subject to extensive government regulation, which increases our costs and could prevent us from selling our products.

Government regulations and agency oversight apply to every aspect of our business, including testing, manufacturing, safety and environmental controls, efficacy, labeling, advertising, promotion, record keeping, the sale and distribution of products and samples. We are also subject to government regulation over the prices we charge and the rebates we offer to customers. Complying with government regulation substantially increases the cost of developing, manufacturing and selling our products.

In the United States, we must obtain approval from the FDA for each product that we market. Competing in the ophthalmic products industry requires us to continuously introduce new or improved products and processes, and to submit these to the FDA for approval. Obtaining FDA approval is a long and expensive process, and approval is never certain. In addition, our operations in the United States are subject to periodic inspection by the FDA. Such inspection may result in the FDA ordering changes in our business practices, which changes could be costly and have a material adverse effect on our business and results of operations. In particular, we received Warning Letters from the FDA on December 29, 2003 and April 26, 2004, and FDA 483 Inspectional Observations on September 23, 2004, requiring us to take corrective action as discussed elsewhere in this report.

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, the potential sales of the product and its value to us can be substantially reduced. Even if the FDA or another regulatory agency approves a product, the approval may limit the indicated uses of the product, or may otherwise limit our ability to promote, sell and distribute the product, or may require post-marketing studies. If we cannot obtain regulatory approval of our new products, or if the approval is too narrow, we will not be able to market these products, which would eliminate or reduce our potential sales and earnings.

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We depend on proprietary technologies, but may not be able to protect our intellectual property rights adequately.

We have numerous patents and pending patent applications. We rely on a combination of contractual provisions, confidentiality procedures and patent, trademark, copyright and trade secrecy laws to protect the proprietary aspects of our technology. These legal measures afford limited protection and may not prevent our competitors from gaining access to our intellectual property and proprietary information. Any of our patents may be challenged, invalidated, circumvented or rendered unenforceable. Furthermore, we cannot be certain that any pending patent application held by us will result in an issued patent or that if patents are issued to us, the patents will provide meaningful protection against competitors or competitive technologies. Litigation may be necessary to enforce our intellectual property rights, to protect our trade secrets and to determine the validity and scope of our proprietary rights. Any litigation could result in substantial expense, may reduce our profits and may not adequately protect our intellectual property rights. In addition, we may be exposed to future litigation by third parties based on claims that our products infringe their intellectual property rights. This risk is exacerbated by the fact that the validity and breadth of claims covered by patents in our industry may involve complex legal issues that are not fully resolved.

Any litigation or claims against us, whether or not successful, could result in substantial costs and harm our reputation. In addition, intellectual property litigation or claims could force us to do one or more of the following: to cease selling or using any of our products that incorporate the challenged intellectual property, which would adversely affect our revenue; to negotiate a license from the holder of the intellectual property right alleged to have been infringed, which license may not be available on reasonable terms, if at all; or to redesign our products to avoid infringing the intellectual property rights of a third party, which may be costly and time-consuming or impossible to accomplish.

We may not successfully develop and launch replacements for our products that lose patent protection.

Most of our products are covered by patents that give us a degree of market exclusivity during the term of the patent. We have also earned revenue in the past by licensing some of our patented technology to other ophthalmic companies. The legal life of a patent is 20 years from application. Patents covering our products will expire from this year through the next 20 years. Upon patent expiration, our competitors may introduce products using the same technology. As a result of this possible increase in competition, we may need to charge a lower price in order to maintain sales of our products, which could make these products less profitable. If we fail to develop and successfully launch new products prior to the expiration of patents for our existing products, our sales and profits with respect to those products could decline significantly. We may not be able to develop and successfully launch more advanced replacement products before these and other patents expire.

Risks Related to Ownership of Our Common Stock

Our Certificate of Incorporation could delay or prevent an acquisition or sale of our company.

Our Certificate of Incorporation empowers the Board of Directors to establish and issue a class of preferred stock, and to determine the rights, preferences and privileges of the preferred stock. We also have a Stockholders Rights Plan, which could discourage a third party from making an offer to acquire us. These provisions give the Board of Directors the ability to deter, discourage or make more difficult a change in control of our company, even if such a change in control would be in the interest of a significant number of our stockholders or if such a change in control would provide our stockholders with a substantial premium for their shares over the then-prevailing market price for the common stock.

Our bylaws contain other provisions that could have an anti-takeover effect, including the following:

only one of the three classes of directors is elected each year;

stockholders have limited ability to remove directors;

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stockholders cannot call a special meeting of stockholders; and

stockholders must give advance notice to nominate directors.

Anti-takeover provisions of Delaware law could delay or prevent an acquisition of our company.

We are subject to the anti-takeover provisions of Section 203 of the Delaware General Corporation Law, which regulates corporate acquisitions. These provisions could discourage potential acquisition proposals and could delay or prevent a change in control transaction. They could also have the effect of discouraging others from making tender offers for our Common Stock or preventing changes in our management.

Future sales of our Common Stock could reduce our stock price.

Our Board of Directors could issue shares of common or preferred stock, to raise additional capital or for other corporate purposes without stockholder approval. In addition, the Board of Directors could designate and sell a class of preferred stock with preferential rights over the Common Stock with respect to dividends or other distributions. Sales of common or preferred stock could dilute the interest of existing stockholders and reduce the market price of our Common Stock. Even in the absence of such sales, the perception among investors that additional sales of equity securities may take place could reduce the market price of our Common Stock.

The market price of our Common Stock is likely to be volatile.

Our stock price has fluctuated widely, ranging from $2.88 to $11.26 during the year ended December 31, 2004. Our stock price could continue to experience significant fluctuations in response to factors such as quarterly variations in operating results, operating results that vary from the expectations of securities analysts and investors, changes in financial estimates, changes in regulatory status, changes in market valuations of competitors, announcements by us or our competitors of a material nature, additions or departures of key personnel, future sales of Common Stock and stock volume fluctuations. Also, general political and economic conditions such as recession or interest rate fluctuations may adversely affect the market price of our stock.

Foreign Exchange

Management does not believe that the fluctuation in the value of the dollar in relation to the currencies of its suppliers or customers in the last three fiscal years has adversely affected the Company s ability to purchase or sell products at agreed upon prices. No assurance can be given, however, that adverse currency exchange rate fluctuations will not occur in the future, which would affect the Company s operating results.

Inflation

Management believes inflation has not had a significant impact on the Company s operations during the past three years.

New Accounting Pronouncements

In October 2004, the American Jobs Creation Act of 2004 (Act) became effective in the U.S. Two provisions of the Act may impact the Company s provision (benefit) for income taxes in future periods, namely those related to the qualified production activities deduction (QPA) and foreign earnings repatriation (FER).

The QPA will be effective for the Company s U.S. federal tax return year beginning after December 31, 2004. In summary, the Act provides for a percentage deduction of earnings from qualified production activities, as defined, commencing with an initial deduction of 3 percent for tax years beginning after 2009, with the result that the statutory federal tax rate currently applicable to the Company s qualified production activities of 35 percent could be reduced initially to 33.95 percent and ultimately to 31.85 percent. However, the Act also provides for the phased elimination of the extraterritorial income exclusion provision of the Internal Revenue Code, which have previously resulted in tax benefits to the Company. Due to the interaction

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of the law provisions noted above as well as the particulars of the Company s tax position, the ultimate effect of the QPA on the Company s future provision (benefit) for income taxes has not been determined at this time. The Financial Accounting Standards Board (FASB) issued FASB Staff Position FAS 109-1, Application of FASB Statement No. 109, Accounting for Income Taxes, to the Tax Deduction on Qualified Production Activities Provided by the American Jobs Creation Act of 2004 (FSP 109-1), in December 2004. FSP 109-1 requires that tax benefits resulting from the QPA should be recognized no earlier than the year in which they are reported in the entity s tax return, and that there is to be no revaluation of recorded deferred tax assets and liabilities as would be the case had there been a change in an applicable statutory rate.

The FER provision of the Act provides generally for a one-time 85 percent dividends received deduction for qualifying repatriations of foreign earnings to the U.S. Qualified repatriated funds must be reinvested in the U.S. in certain qualifying activities and expenditures, as defined by the Act. In December 2004, the FASB issued FASB Staff Position FAS 109-2, Accounting and Disclosure Guidance for the Foreign Earnings Repatriation Provision within the American Jobs Creation Act of 2004 (FSP 109-2). FSP 109-2 allows additional time for entities potentially impacted by the FER provision to determine whether any foreign earnings will be repatriated under this provision. At this time, the Company has not undertaken an evaluation of the application of the FER provision and any potential benefits of effecting such repatriations under this provision. Numerous factors, including previous actual and deemed repatriations under federal tax law provisions, are factors impacting the availability of the FER provision to the Company and its potential benefit to the Company, if any. The Company intends to examine the issue and will provide updates in subsequent periods.

In November 2004, the FASB issued Statement of Financial Accounting Standards (SFAS) No. 151, Inventory Costs. This statement amends the guidance in ARB No. 43, Chapter 4, Inventory Pricing, to clarify the accounting for abnormal amounts of idle facility expense, freight, handling costs, and wasted materials (spoilage). SFAS No. 151 requires that those items be recognized as current-period charges. In addition, this statement requires that allocation of fixed production overheads to costs of conversions be based upon the normal capacity of the production facilities. The provisions of SFAS No. 151 are effective for inventory cost incurred in fiscal years beginning after June 15, 2005. As such, the Company is required to adopt these provisions at the beginning of fiscal 2006. The adoption of this pronouncement is not expected to have a material effect on the Company s financial statements.

In December 2004, the FASB issued SFAS No. 123R, Share-Based Payment. This statement is a revision of SFAS No. 123, Accounting for Stock-Based Compensation, and supersedes APB Opinion No. 25, Accounting for Stock Issued to Employees, and its related implementation guidance. SFAS No. 123R addresses all forms of share-based payment (SBP) awards including shares issued under employee stock purchase plans, stock options, restricted stock and stock appreciation rights. Under SFAS No. 123R, SBP awards result in a cost that will be measured at fair value on the awards grant date, based on the estimated number of awards that are expected to vest. This statement is effective for public entities as of the beginning of the next fiscal year that begins after June 15, 2005. The Company has not quantified the potential effect of adoption of SFAS No. 123R, but believes that the adoption of this statement will result in a decrease to earnings.

In December 2004, the FASB issued SFAS No. 153, Exchange of Nonmonetary Assets. This statement amends Opinion 29 to eliminate the exception for nonmonetary exchanges of similar productive assets and replaces it with a general exception for exchanges of nonmonetary assets that do not have commercial substance. A nonmonetary exchange has commercial substance if the future cash flows of the entity are expected to change significantly as a result of the exchange. The provisions of this statement are effective for nonmonetary asset exchanges occurring in fiscal periods beginning after June 15, 2005. Earlier application is permitted for nonmonetary asset exchanges occurring in fiscal periods beginning after December 16, 2004. The provisions of this statement should be applied prospectively. The adoption of this pronouncement is not expected to have a material effect on the Company s financial statements.

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

In the normal course of business, our operations are exposed to risks associated with fluctuations in interest rates and foreign currency exchange rates. The Company manages its risks based on management s judgment of the appropriate trade-off between risk, opportunity and costs. Management does not believe that these market risks are material to the results of operations or cash flows of the Company, and, accordingly, does not generally enter into interest rate or foreign exchange rate hedge instruments.

Interest rate risk. Our $3.0 million of debt is based on the borrowings of our international subsidiaries. The majority of our international borrowings bear an interest rate that is linked to Euro market conditions and, thus, our interest rate expense will fluctuate with changes in those conditions. If interest rates were to increase or decrease by 1% for the year, our annual interest rate expense would increase or decrease by approximately $30,000.

Foreign currency risk. Our international subsidiaries operate in and are net recipients of currencies other than the U.S. dollar and, as such, our revenues benefit from a weaker dollar and are adversely affected by a stronger dollar relative to major currencies worldwide (primarily, the Euro and Australian dollar). Accordingly, changes in exchange rates, and particularly the strengthening of the US dollar, may negatively affect our consolidated sales and gross profit as expressed in U.S. dollars. Additionally, as of December 31, 2004, all of our debt is denominated in Swiss Francs and as such, we are subject to fluctuations of the Swiss Franc as compared to the U.S. dollar in converting the value of the debt to U.S. dollars. The U.S. dollar value of the debt is increased by a weaker dollar and decreased by a stronger dollar relative to the Swiss Franc.

In the normal course of business, we also face risks that are either non-financial or non-quantifiable. Such risks include those set forth in Item 7. Management s Discussion and Analysis of Financial Condition and Results of Operations Risk Factors.

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

Financial Statements and the Report of Independent Registered Public Accounting Firm are filed with this Annual Report on Form 10-K in a separate section following Part IV, as shown on the index under Item 15 of this Annual Report.

Item 9. ***Changes in and Disagreements with Accountants on Accounting and Financial Disclosure***

Not applicable.

Item 9A. ***Controls and Procedures***

Attached as exhibits to this Form 10-K are certifications of STAAR s Chief Executive Officer (CEO) and Chief Financial Officer (CFO), which are required in accordance with Rule 13a-14(a) of the Securities Exchange Act of 1934, as amended (the Exchange Act). This Controls and Procedures section includes information concerning the controls and controls evaluation referred to in the certifications. The section following Part IV of this Form 10-K sets forth the report of BDO Seidman LLP, our independent registered public accounting firm, regarding its audit of STAAR s consolidated financial statements included in this Form 10-K and its attestation of management s assessment of internal control over financial reporting set forth below in this section. This section should be read in conjunction with the certifications and the BDO Seidman report for a more complete understanding of the topics presented.

Evaluation of Disclosure Controls and Procedures

The Company s Chief Executive Officer, David Bailey, and Chief Financial Officer, John Bily, with the participation of the Company s management, carried out an evaluation of the effectiveness of the Company s disclosure controls and procedures pursuant to Exchange Act Rule 13a-15(b). Based upon that evaluation, the Chief Executive Officer and the Chief Financial Officer believe that, as of the end of the period covered by this report, the Company s disclosure controls and procedures are effective in making known to them material

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information relating to the Company (including its consolidated subsidiaries) required to be included in this report.

Changes in Internal Control over Financial Reporting

There was no change during the fiscal quarter ended December 31, 2004, known to the Chief Executive Officer or the Chief Financial Officer, that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Management Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Exchange Act Rule 13a-15(f).

Management assessed the effectiveness of our internal control over financial reporting as of December 31, 2004, the end of our fiscal year. Management based its assessment on criteria established in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission.

Based on this assessment, management has concluded that our internal control over financial reporting was effective as of the end of the fiscal year ended December 31, 2004.

BDO Seidman LLP, the independent registered public accounting firm that audited and reported on the consolidated financial statements of the Company contained in this report, has issued an attestation report on management s assessment of our internal control over financial reporting, which follows Part IV of this Form 10-K.

Inherent Limitations on Effectiveness of Controls

The Company s management, including the CEO and CFO, does not expect that our Disclosure Controls or our internal control over financial reporting will prevent or detect all error and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system s objectives will be met. The design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Further, because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud, if any, within the company have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty and that breakdowns can occur because of simple error or mistake. Controls can also be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the controls. The design of any system of controls is based in part on certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Projections of any evaluation of controls effectiveness to future periods are subject to risks. Over time, controls may become inadequate because of changes in conditions or deterioration in the degree of compliance with policies or procedures.

Item 9B. ***Other Information***

Not applicable.

PART III

Item 10. ***Directors and Executive Officers of the Registrant***

The information in Item 10 is incorporated herein by reference to the section entitled Proposal One Election of Directors contained in the proxy statement (the Proxy Statement) for the 2005 annual meeting

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of stockholders to be filed with the Securities and Exchange Commission within 120 days of the close of the fiscal year ended December 31, 2004.

Item 11. ***Executive Compensation***

The information in Item 11 is incorporated herein by reference to the section entitled Proposal One Election of Directors contained in the Proxy Statement.

Item 12. ***Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters***

The information in Item 12 is incorporated herein by reference to the section entitled General Information Security Ownership of Certain Beneficial Owners and Management and Proposal One Election of Directors contained in the Proxy Statement.

Item 13. ***Certain Relationships and Related Transactions***

The information in Item 13 is incorporated herein by reference to the section entitled Proposal One Election of Directors contained in the Proxy Statement.

Item 14. ***Principal Accountant Fees and Services***

The information in Item 14 is incorporated herein by reference to the section entitled Proposal Two Ratification of the Appointment of Independent Registered Public Accounting Firm contained in the Proxy Statement.

PART IV

Item 15. ***Exhibits and Financial Statement Schedules***

		Page
(1)	Financial statements required by Item 15 of this form are filed as a separate part of this report following Part IV	
	Report of Independent Registered Public Accounting Firm	F-2
	Report of Independent Registered Public Accounting Firm	F-3
	Consolidated Balance Sheets at December 31, 2004 and January 2, 2004	F-4
	Consolidated Statements of Operations for the years ended December 31, 2004, January 2, 2004, and January 3, 2003	F-5
	Consolidated Statements of Changes in Stockholders Equity for the years ended December 31, 2004, January 2, 2004, and January 3, 2003	F-6
	Consolidated Statements of Cash Flows for the years ended December 31, 2004, January 2, 2004, and January 3, 2003	F-7
	Notes to Consolidated Financial Statements	F-8
(2)	Schedules required by Regulation S-X are filed as an exhibit to this report:	
	I. Independent Registered Public Accounting Firm Report on Schedule	F-31
	II. Schedule II Valuation and Qualifying Accounts and Reserves	F-32

Schedules not listed above have been omitted because the information required to be set forth therein is not applicable or is shown in the financial statements and the notes thereto.

(3) *Exhibits*

3.1	Certificate of Incorporation, as amended(8)
3.2	By-laws, as amended(9)

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4.1	1991 Stock Option Plan of STAAR Surgical Company(2)
4.2	1995 STAAR Surgical Company Consultant Stock Plan(3)
4.3	1996 STAAR Surgical Company Non-Qualified Stock Plan(4)
4.4	Stockholders Rights Plan, dated effective April 20, 1995(9)
4.5	1998 STAAR Surgical Company Stock Plan, adopted April 17, 1998(5)
4.6	Form of Certificate for Common Stock, par value $0.01 per share(14)
4.7	2003 Omnibus Equity Incentive Plan and form of Option Grant and Stock Option Agreement(13)
4.8	Amendment No. 1 to Stockholders Rights Plan, dated April 21, 2003(15)
4.9	Registration Rights Agreement, dated June 4, 2004(19)
10.1	Joint Venture Agreement, dated May 23, 1988, among the Company, Canon Sales Co, Inc. and Canon, Inc., and Exhibit B, Technical Assistance and License Agreement, dated September 6, 1988, between the Company and Canon Staar Co., Inc.(7)
10.2	Settlement Agreement among the Company, Canon, Inc., Canon Sales Co., Inc., and Canon Staar Company, Inc. dated September 28, 2001(10)
10.3	Indenture of Lease dated September 1, 1993, between the Company and FKT Associates and First through Third Additions Thereto(9)
10.4	Second Amendment to Indenture of Lease dated September 21, 1998, between the Company and FKT Associates(9)
10.5	Third Amendment to Indenture of Lease dated October 13, 2003, by and between the Company and FKT Associates(17)
10.6	Indenture of Lease dated October 20, 1983, between the Company and Dale E. Turner and Francis R. Turner and First through Fifth Additions Thereto(6)
10.7	Sixth Lease Addition to Indenture of Lease dated October 13, 2003, by and between the Company and Turner Trust UTD Dale E. Turner March 28, 1984(17)
10.8	Standard Industrial/ Commercial Multi-Tenant Lease-Gross dated April 5, 2000, entered into between the Company and Kilroy Realty, L.P.(9)
10.9	Amendment No. 1 to Standard Industrial/ Commercial Multi-Tenant Lease dated January 3, 2003, by and between the Company and California Rosen(17)

10.10	Lease Agreement dated July 12, 1994, between STAAR Surgical AG and Calderari and Schwab AG/ SA(22)
10.11	Supplement #1 dated July 10, 1995, to the Lease Agreement of July 12, 1994, between STAAR Surgical AG and Calderari and Schwab AG/SA(22)
10.12	Supplement #2 dated August 2, 1999, to the Lease Agreement of July 12, 1994, between STAAR Surgical AG and Calderari and Schwab AG/SA(22)
10.13	Commercial Lease Agreement dated November 29, 2000, between Domilens GmbH and DePfa Deutsche Pfandbriefbank AG(22)
10.14	Patent License Agreement, dated May 24, 1995, with Eye Microsurgery Intersectoral Research and Technology Complex(16)
10.15	Patent License Agreement, dated January 1, 1996, with Eye Microsurgery Intersectoral Research and Technology Complex(9)
10.16	Promissory Note dated June 16, 1999, from Peter J. Utrata to the Company(8)
10.17	Stock Pledge Agreement dated June 16, 1999, by Peter J. Utrata in favor of the Company(8)
10.18	Promissory Note dated June 2, 2000, from Peter J. Utrata to the Company(9)
10.19	Stock Pledge Agreement dated June 2, 2000, between the Company and Peter J. Utrata(9)
10.20	Mortgage dated July 16, 2004, between the Company and Peter J. Utrata(22)
10.21	Forbearance Agreement dated July 22, 2004, between the Company and Peter J. Utrata(22)
10.22	Employment Agreement dated December 19, 2000, between the Company and David Bailey(9)
10.23	Stock Option Plan and Agreement for Chief Executive Officer dated November 13, 2001, between the Company and David Bailey(10)

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10.24	Stock Option Certificate dated August 9, 2001, between the Company and David Bailey(22)
10.25	Stock Option Certificate dated January 2, 2002, between the Company and David Bailey(22)
10.26	Stock Option Certificate dated February 14, 2003, between the Company and David Bailey(22)
10.27	Amended and Restated Stock Option Certificate dated February 12, 2003, between the Company and David Bailey(22)
10.28	Stock Option Certificate dated May 9, 2000, between the Company and Volker Anhaeusser(22)
10.29	Stock Option Certificate dated May 31 2000, between the Company and Volker Anhaeusser(22)
10.30	Stock Option Certificate dated May 30, 2002, between the Company and Volker Anhaeusser(22)
10.31	Stock Option Agreement dated November 13, 2001, between the Company and David R. Morrison(10)
10.32	Stock Option Certificate dated February 13, 2003, between the Company and Donald Duffy(22)
10.33	Employment Agreement dated January 3, 2002, between the Company and John Bily(11)
10.34	Stock Option Certificate dated January 18, 2002, between the Company and John C. Bily(22)
10.35	Amended and Restated Stock Option Certificate dated February 12, 2003, between the Company and John C. Bily(22)
10.36	Offer of Employment dated July 12, 2002, from the Company to Nick Curtis(22)
10.37	Amendment to Offer of Employment dated February 14, 2003 from the Company to Nick Curtis(22)
10.38	Stock Option Certificate dated February 14, 2003, between the Company and Nicholas Curtis(22)
10.39	Amended and Restated Stock Option Certificate dated February 12, 2003, between the Company and Nicholas Curtis(22)
10.40	Employment Agreement dated March 18, 2005, between the Company and Tom Paul(22)

10.41	Employment Agreement dated March 18, 2005, between the Company and James Farnworth(22)
10.42	Form of Indemnification Agreement between the Company and certain officers and directors(22)
10.43	Managing Director s Contract of Employment, dated June 22, 1993, between Domilens and Guenther Roepstorff(22)
10.44	Supplementary Agreement #1 to the Managing Director s Contract of Employment, dated November 25, 1997, between STAAR Surgical AG and Guenther Roepstorff(22)
10.45	Supplementary Agreement #2 to the Managing Director s Contract of Employment dated January 1, 1998, between Domilens and Guenther Roepstorff(22)
10.46	Supplementary Agreement #3 to the Managing Director s Contract of Employment dated January 1, 2003, between Domilens and Guenther Roepstorff(22)
10.47	Employment Agreement dated May 5, 2004, between the ConceptVision Australia Pty Limited ACN 006 391 928 and Philip Butler Stoney(18)
10.48	Employment Agreement dated May 5, 2004, between the ConceptVision Australia Pty Limited ACN 006 391 928 and Robert William Mitchell(18)
#10.49	Assignment Agreement of the Share Capital of Domilens Vertrieb fuer medizinische Produkte GmbH dated January 3, 2003, between STAAR Surgical AG and Guenther Roepstorff(12)
10.50	Assignment Agreement of the Share Capital of ConceptVision Australia Pty Limited ACN 006 391 928, dated May 5, 2004, between the Company and Philip Butler Stoney and Robert William Mitchell(18)
10.51	Addendum to the Assignment Agreement of the Share Capital of ConceptVision Australia Pty Limited ACN 006 391 928, dated May 5, 2004, between the Company and Philip Butler Stoney and Robert William Mitchell(18)
10.52	Form of Purchase Agreement dated June 11, 2003, entered into between the Company and Crestwood Capital Partners, LP; Crestwood Capital International, Ltd; Crestwood Capital Partners II, LP; RS Emerging Growth Pacific Partners Master Fund Unit Trust; RS Emerging Growth Pacific Partners LP, Prism Partners I, LP; Prism Partners II Offshore Fund; Prism Partners Offshore Fund; Vertical Ventures Investments, LLC; Smithfield Fiduciary, LLC, individually(21)

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10.53	Stock Purchase Agreement dated June 4, 2004, between the Company and Andesite Management, L.P., Colonial Fund LLC, Domain Public Equity Partners, L.P., Fortis L Fund Equity Pharma World, Fortis L Fund Opportunity World, Heartland Group, Inc., ProMed Offshore Fund, Ltd., ProMed Partners, L.P., ProMed Partners II, L.P., Sagitta Asset Management Ltd., SF Capital Partners, Ltd., Special Situations Cayman Fund L.P., Special Situations Fund III, L.P., Special Situations Private Equity Fund, L.P., Ursus Capital, L.P., Ursus Offshore, Ltd., Zeke, LP(19)
10.54	Master Credit Agreement dated August 2, 2004, between STAAR Surgical AG and UBS AG(20)
10.55	Credit Agreement effective January 13, 2003, between Domilens Gmbh and Postbank(12)
10.56	Promissory Note dated March 29, 2002, between the Company and Pollet & Richardson(22)
#10.57	Security Agreement dated March 29, 2002, between the Company and Pollet & Richardson(12)
14.1	Code of Ethics(22)
21.1	List of Significant Subsidiaries(22)
23.1	Consent of BDO Seidman, LLP**
31.1	Certification Pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934, Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002**
31.2	Certification Pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934, Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002**
32.1	Certification Pursuant to 18 U.S.C. Section 1350, Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002**

** Filed herewith

Management contract or compensatory plan or arrangement

All schedules and or exhibits have been omitted. Any omitted schedule or exhibit will be furnished supplementally to the Securities and Exchange Commission upon request

(2) Incorporated by reference from the Company s Registration Statement on Form S-8, File No. 033-76404, as filed on March 11, 1994.

(3) Incorporated by reference from the Company s Registration Statement on Form S-8, File No. 033-60241, as filed on June 15, 1995.

(4) Incorporated by reference from the Company s Annual Report on Form 10-K, for the year ended January 3, 1997, as filed on April 2, 1997.

(5) Incorporated by reference from the Company s Proxy Statement, for its Annual Meeting of Stockholders held on May 29, 1998, as filed on May 1, 1998.

(6) Incorporated by reference from the Company s Annual Report on Form 10-K, for the year ended January 2, 1998, as filed on April 1, 1998.

(7) Incorporated by reference from the Company s Annual Report on Form 10-K, for the year ended January 1, 1999, as filed on April 1, 1999.

(8) Incorporated by reference from the Company s Annual Report on Form 10-K, for the year ended December 31, 1999, as filed on March 30, 2000.

(9) Incorporated by reference from the Company s Annual Report on Form 10-K, for the year ended December 29, 2000, as filed on March 29, 2001.

(10) Incorporated by reference to the Company s Annual Report on Form 10-K, for the year ended December 28, 2001, as filed on March 28, 2002.

(11) Incorporated by reference to the Company s Quarterly Report, for the period ended June 28, 2002, as filed on August 12, 2002.

(12) Incorporated by reference to the Company s Annual Report on Form 10-K, for the year ended January 3, 2003, as filed on April 3, 2003.

(13) Incorporated by reference from the Company s Proxy Statement, for its Annual Meeting of Stockholders held on June 18, 2003, as filed on May 19, 2003.

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(14) Incorporated by reference to Exhibit 4.1 to Amendment No. 1 to the Company s Registration Statement on Form 8-A/ A, as filed on April 18, 2003.

(15) Incorporated by reference to the Company s Quarterly Report, for the period ended April 4, 2003, as filed on May 19, 2003.

(16) Incorporated by reference from the Company s Annual Report on Form 10-K/ A, for the year ended December 29, 2000, as filed on May 9, 2001.

(17) Incorporated by reference to the Company s Annual Report on Form 10-K, for the year ended January 2, 2004, as filed on March 17, 2004.

(18) Incorporated by reference to the Company s Quarterly Report, for the period ended April 2, 2004, as filed on May 12, 2004.

(19) Incorporated by reference to the Company s Current Report on Form 8-K, as filed on June 9, 2004.

(20) Incorporated by reference to the Company s Quarterly Report, for the period ended October 1, 2004, as filed on November 10, 2004.

(21) Incorporated by reference to the Company s Current Report on Form 8-K, as filed on June 13, 2003.

(22) Incorporated by reference to the Company s Annual Report on Form 10-K, for the year ended December 31, 2004, as filed on March 30, 2005.

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SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this Amendment No. 1 to its Annual Report on Form 10-K to be signed on its behalf by the undersigned, thereunto duly authorized.

STAAR SURGICAL COMPANY

By: /s/ David Bailey

David Bailey
President and Chief Executive Officer
(principal executive officer)

Date: April 20, 2005

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STAAR SURGICAL COMPANY AND SUBSIDIARIES
CONSOLIDATED FINANCIAL STATEMENTS
YEARS ENDED DECEMBER 31, 2004,
JANUARY 2, 2004 AND JANUARY 3, 2003

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STAAR SURGICAL COMPANY AND SUBSIDIARIES
REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Stockholders
STAAR Surgical Company
Monrovia, CA

We have audited the accompanying consolidated balance sheets of STAAR Surgical Company and subsidiaries as of December 31, 2004 and January 2, 2004, and the related consolidated statements of operations, stockholders equity, and cash flows for each of the three years in the period ended December 31, 2004. These financial statements are the responsibility of the Company s management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of STAAR Surgical Company and subsidiaries as of December 31, 2004 and January 2, 2004, and the consolidated results of their operations and their cash flows for each of the three years in the period ended December 31, 2004, in conformity with accounting principles generally accepted in the United States of America.

We also have audited, in accordance with standards of the Public Company Accounting Oversight Board (United States), the effectiveness of the Company s internal control over financial reporting as of December 31, 2004, based on criteria established in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 16, 2005 expressed an unqualified opinion thereon.

/s/ BDO Seidman, LLP

Los Angeles, California
March 16, 2005, except for Note 19
which is as of April 4, 2005.

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STAAR SURGICAL COMPANY AND SUBSIDIARIES
REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Stockholders
STAAR Surgical Company
Monrovia, CA

We have audited management s assessment, included in the accompanying Management s Report on Internal Control over Financial Reporting included in Item 9A, that STAAR Surgical Company maintained effective internal control over financial reporting as of December 31, 2004, based on criteria established in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). STAAR Surgical Company s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express an opinion on management s assessment and an opinion on the effectiveness of the company s internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, evaluating management s assessment, testing and evaluating the design and operating effectiveness of internal control, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company s internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company s internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company s assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, management s assessment that STAAR Surgical Company maintained effective internal control over financial reporting as of December 31, 2004, is fairly stated, in all material respects, based on criteria established in COSO. Also in our opinion, STAAR Surgical Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2004, based on criteria established in COSO.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of STAAR Surgical Company as of December 31, 2004 and January 2, 2004 and the related consolidated statements of income, changes in stockholders equity, and cash flows for each of the three years in the period ended December 31, 2004, and our report dated March 16, 2005, except for Note 19 which is as of April 4, 2005, expressed an unqualified opinion thereon.

/s/ BDO Seidman, LLP

Los Angeles, California
March 16, 2005

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STAAR SURGICAL COMPANY AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
December 31, 2004 and January 2, 2004

	2004	2003
	(In thousands, except par value amounts)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 4,187	$ 7,286
Short-term investments	5,125	
Accounts receivable, less allowance for doubtful accounts and sales returns	6,217	5,675
Inventories	15,084	12,802
Prepaids, deposits and other current assets	1,969	2,001
Total current assets	32,582	27,764
Investment in joint venture	125	397
Property, plant and equipment, net	6,163	6,638
Patents and licenses, net of accumulated amortization of $6,089 and $5,583	5,400	6,059
Goodwill	7,534	6,427
Other assets	169	91
Total assets	$ 51,973	$ 47,376
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Notes payable	$ 3,004	$ 2,950
Accounts payable	5,313	4,544
Other current liabilities	5,162	4,387
Total current liabilities	13,479	11,881
Other long-term liabilities	632	72
Total liabilities	14,111	11,953
Minority interest	22	204
Commitments and contingencies		
Stockholders equity:		
Preferred stock, $.01 par value, 10,000 shares authorized, none issued		
Common stock, $.01 par value; 30,000 shares authorized; issued and outstanding 20,664 and 18,403 shares	207	184
Additional paid-in capital	98,691	85,948
Accumulated other comprehensive income	1,024	572
Accumulated deficit	(60,478)	(49,146)

	39,444	37,558
Notes receivable from officers and directors	(1,604)	(2,339)
Total stockholders equity	37,840	35,219
Total liabilities and stockholders equity	$ 51,973	$ 47,376

See accompanying summary of accounting policies and notes to consolidated financial statements.

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STAAR SURGICAL COMPANY AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS
Years Ended December 31, 2004, January 2, 2004 and January 3, 2003

	2004	2003	2002
		(In thousands, except per share amounts)	
Sales	$ 51,685	$ 50,409	$ 47,880
Royalty and other income		49	368
Total revenues	51,685	50,458	48,248
Cost of sales	25,542	22,621	24,099
Gross profit	26,143	27,837	24,149
Selling, general and administrative expenses:			
General and administrative	9,253	9,343	8,959
Marketing and selling	20,302	19,509	16,833
Research and development	6,246	5,120	4,016
Other charges	500	390	1,454
Total selling, general and administrative expenses	36,301	34,362	31,262
Operating loss	(10,158)	(6,525)	(7,113)
Other income (expense):			
Equity in earnings of joint venture	(191)	11	36
Interest income	219	256	361
Interest expense	(215)	(322)	(579)
Other income (expense)	99	(582)	(603)
Total other expense, net	(88)	(637)	(785)
Loss before income taxes and minority interest	(10,246)	(7,162)	(7,898)
Provision for income taxes	1,057	1,127	8,805
Minority interest	29	68	75
Net loss	$ (11,332)	$ (8,357)	$ (16,778)
Loss per share:			
Basic and diluted	$ (0.58)	$ (0.47)	$ (0.98)
Weighted average shares outstanding			
Basic and diluted	19,602	17,704	17,142

See accompanying summary of accounting policies and notes to consolidated financial statements.

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STAAR SURGICAL COMPANY AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS EQUITY
Years Ended December 31, 2004, January 2, 2004 and January 3, 2003

	Common Stock Shares	Common Stock Par Value	Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated (Deficit)	Notes Receivable	Total
				(In thousands)			
Balance, at December 28, 2001	17,158	$ 172	$ 75,573	$ (1,728)	$ (24,011)	$ (3,864)	$ 46,142
Common stock issued upon exercise of options	5		6				6
Common stock issued as payment for services	39		120				120
Common stock issued pursuant to employment contract	3		12				12
Stock-based consultant expense			236				236
Treasury stock acquired in satisfaction of note receivable	(243)	(3)	(970)			2,129	1,156
Proceeds from notes receivable						96	96
Accrued interest on notes receivable						(242)	(242)
Reversal of notes receivable reserve						(1,814)	(1,814)
Foreign currency translation adjustment				1,617			1,617
Net loss					(16,778)		(16,778)
Balance, at January 3, 2003	16,962	169	74,977	(111)	(40,789)	(3,695)	30,551
Common stock issued upon exercise of warrants	387	4	1,549				1,553
Common stock issued as payment for services	54	1	278				279
Stock-based consultant expense			206				206
Net proceeds from private placement	1,000	10	8,938				8,948
Proceeds from notes receivable						3,270	3,270

Accrued interest on notes receivable						(118)	(118)
Reversal of notes receivable reserve						(1,796)	(1,796)
Foreign currency translation adjustment				683			683
Net loss					(8,357)		(8,357)
Balance, at January 2, 2004	18,403	184	85,948	572	(49,146)	(2,339)	35,219
Common stock issued upon exercise of options	250	3	826				829
Common stock issued as payment for services	11		60				60
Stock-based consultant expense			231				231
Net proceeds from private placement	2,000	20	11,626				11,646
Proceeds from notes receivable						330	330
Accrued interest on notes receivable						(95)	(95)
Notes receivable reserve						500	500
Foreign currency translation adjustment				452			452
Net loss					(11,332)		(11,332)
Balance, at December 31, 2004	20,664	$ 207	$ 98,691	$ 1,024	$ (60,478)	$ (1,604)	$ 37,840

See accompanying summary of accounting policies and notes to consolidated financial statements.

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STAAR SURGICAL COMPANY AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS
Years Ended December 31, 2004, January 2, 2004 and January 3, 2003

	2004	2003	2002
		(In thousands)	
Cash flows from operating activities:			
Net loss	$ (11,332)	$ (8,357)	$ (16,778)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:			
Depreciation of property and equipment	2,005	1,950	2,171
Amortization of intangibles	688	952	933
Write-off of patents		2,102	
Loss on disposal of fixed assets	175	159	
Equity in earnings of joint venture	191	(11)	(36)
Deferred income taxes			9,132
Stock-based consultant expense	231	206	236
Common stock issued for services	60	279	132
Non-cash restructuring and inventory write-down			1,225
Net change in notes receivable reserve	500	(1,364)	
Other	(95)	(124)	(226)
Minority interest	21	104	144
Changes in working capital:			
Accounts receivable	(542)	474	1,462
Inventories	(2,282)	(1,041)	3,108
Prepaids, deposits and other current assets	32	380	(232)
Accounts payable	769	351	(966)
Other current liabilities	775	(206)	264
Net cash provided by (used in) operating activities	(8,804)	(4,146)	569
Cash flows from investing activities:			
Acquisition of property and equipment	(1,705)	(1,309)	(874)
Acquisition of patents and licenses	(16)	(75)	(75)
Purchase of short-term investments	(8,000)		
Sale of short-term investments	2,875		
Purchase of minority interest in subsidiary	(768)		
Proceeds from notes receivable and other	330	3,270	10
Change in other assets	(91)	189	493
Dividends received from joint venture	81	76	40
Net cash provided by (used in) investing activities	(7,294)	2,151	(406)
Cash flows from financing activities:			
Net borrowings (payments) under notes payable and long-term debt	72	(2,912)	(2,598)
Restricted cash			2,000
Proceeds from the exercise of stock options and warrants	829	1,553	6

Net proceeds from private placement	11,646	8,948	
Net cash provided by (used in) financing activities	12,547	7,589	(592)
Effect of exchange rate changes on cash and cash equivalents	452	683	585
Increase (decrease) in cash and cash equivalents	(3,099)	6,277	156
Cash and cash equivalents, at beginning of year	7,286	1,009	853
Cash and cash equivalents, at end of year	$ 4,187	$ 7,286	$ 1,009

See accompanying summary of accounting policies and notes to consolidated financial statements.

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STAAR SURGICAL COMPANY AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
Years Ended December 31, 2004 and January 2, 2004

Note 1 Significant Accounting Policies

Organization and Description of Business

STAAR Surgical Company (the Company), a Delaware corporation, was incorporated in 1982 for the purpose of developing, producing, and marketing intraocular lenses (IOLs) and other products for minimally invasive ophthalmic surgery. The Company has evolved to become a developer, manufacturer and global distributor of products used by ophthalmologists and other eye care professionals to improve or correct vision in patients with cataracts, refractive conditions and glaucoma. Products sold by the Company for use in restoring vision adversely affected by cataracts include its line of silicone and Collamer IOLs, the Preloaded Injector, a three-piece silicone IOL preloaded into a single-use disposable injector, the SonicWAVE™ Phacoemulsification System, STAARVISC™ II, a viscoelastic material, and Cruise Control, a disposable filter which allows for a significantly faster, cleaner phacoemulsification procedure and is compatible with all phacoemulsification equipment utilizing Venturi and peristaltic pump technologies. Products sold by the Company for use in correcting refractive conditions such as myopia (near-sightedness), hyperopia (far-sightedness) and astigmatism include the VISIAN™ ICL (ICL) and the VISIAN TICL (TICL). The Company s AquaFlow™ Collagen Glaucoma Drainage Device is surgically implanted in the outer tissues of the eye to maintain a space that allows increased drainage of intraocular fluid thereby reducing intraocular pressure, which otherwise may lead to deterioration of vision in patients with glaucoma. The Company also sells other instruments, devices and equipment that are manufactured either by the Company or by others in the ophthalmic products industry.

The Company s only subsidiary is STAAR Surgical AG, a wholly owned subsidiary formed in Switzerland to develop, manufacture and distribute certain of the Company s products worldwide, including the ICL and the AquaFlow device. STAAR Surgical AG also controls a major European sales subsidiary that distributes both the Company s products and products from various other manufacturers. Investment in the subsidiary was increased from 80% to 100% during the fourth quarter of 2002, when STAAR Surgical AG purchased the remaining shares of the subsidiary (see Note 9).

Canon Staar Joint Venture

In 1988, the Company entered into a joint venture with Canon Inc. and Canon Sales Co., Inc. for the principal purpose of designing, manufacturing, and selling in Japan intraocular lenses and other ophthalmic products. The joint venture will market its products worldwide through Canon, Canon Sales or STAAR or such other distributors as the Board of Directors of the joint venture may approve. The terms of any distribution arrangement will require the unanimous approval of the Board of Directors of the joint venture. Each joint venture party is entitled to appoint one member of the Board of Directors of the joint venture. Certain matters require the unanimous approval of the directors. Upon the occurrence of certain events, including the merger, sale of substantially all of the assets or change in the management of one of the parties, any of the other parties may have the right to acquire the first party s interest in the joint venture at book-value. The Company also granted to the joint venture a perpetual exclusive license under the Licensed Technology (as defined in the license agreement) to make and sell any products in Japan, and a perpetual non-exclusive license to do so in the rest of the world.

In 2001, the parties entered into a settlement agreement whereby (i) they reconfirmed the joint venture agreement and the license agreement, (ii) they agreed that the Company would promptly commence the transfer of the Licensed Technology to the joint venture, (iii) the Company granted the joint venture an exclusive license to make any products in China and sell such products in Japan and China (subject to the existing rights of third parties), (iv) the Company agreed to provide the joint venture with raw materials, (v) the joint venture granted Canon Sales Co., Inc. the right to distribute its products in Japan on specified terms, and (iv) the parties settled certain patent disputes.

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STAAR SURGICAL COMPANY AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Basis of Presentation

The accompanying consolidated financial statements include the accounts of the Company, its wholly owned and its majority owned subsidiaries. All significant intercompany balances and transactions have been eliminated in consolidation. Assets and liabilities of foreign subsidiaries are translated at rates of exchange in effect at the close of the year. Revenues and expenses are translated at the weighted average of exchange rates in effect during the year. The resulting translation gains and losses are deferred and are shown as a separate component of stockholders equity as accumulated other comprehensive income (loss). During 2004, 2003 and 2002, the net foreign translation gain was $452,000, $683,000 and $585,000, respectively, and net foreign currency transaction loss was $190,000, $107,000 and $458,000, respectively.

Investment in the Company s joint venture, Canon Staar Co., Inc., is accounted for using the equity method of accounting (see Note 6).

The Company s fiscal year ends on the Friday nearest December 31 and each of the Company s quarterly reporting periods generally consists of 13 weeks.

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STAAR SURGICAL COMPANY AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Revenue Recognition

The Company recognizes revenue when realized or realizable and earned, which is when the following criteria are met: persuasive evidence of an arrangement exists; delivery has occurred; the sale price is fixed and determinable; and collectibility is reasonably assured. We record revenue from product sales when title and risk of ownership has been transferred to the customer, which is typically upon delivery to the customer. The exception to this recognition policy is revenue from intraocular lenses distributed on a consignment basis, which is recognized upon notification of implantation in a patient.

The Company may bundle the sale of phacoemulsification equipment to customers with multi-year agreements to purchase minimum quantities of foldable IOLs. The Company recognizes the revenue from the equipment based on monthly purchases of minimum quantities of IOLs over the life of the agreement.

Revenue from license and technology agreements is recorded as income, when earned, according to the terms of the respective agreements.

The Company generally permits returns of product if such product is returned within the time allowed by the Company, and in good condition. Allowances for returns are provided for based upon an analysis of our historical patterns of returns matched against the sales from which they originated. To date, historical product returns have been within the Company s estimates.

The Company maintains provisions for uncollectible accounts for estimated losses resulting from the inability of its customers to remit payments. The Company continuously monitors collections and payments from its customers and maintains a provision for estimated credit losses based upon its historical experience and any specific customer collection issues that have been identified.

Concentration of Credit Risk

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

Income Taxes

The Company recognizes deferred tax assets and liabilities for temporary differences between the financial reporting basis and the tax basis of the Company s assets and liabilities along with net operating loss and credit carryforwards. A valuation allowance is recognized if, based on the weight of available evidence, it is more likely than not that some portion or all of the deferred tax asset may not be realized. The impact on deferred taxes of changes in tax rates and laws, if any, are applied to the years during which temporary differences are expected to be settled and reflected in the financial statements in the period of enactment.

Cash, Cash Equivalents, and Restricted Cash

The Company considers all highly liquid investments purchased with a maturity of three months or less to be cash equivalents.

Short-Term Investments

Short-term investments are classified as available for sale and are reported at fair value. Unrealized holding gains and losses, if any, net of the related income tax effect, are excluded from income and are reported in other comprehensive income. Realized gains and losses are included in income on the specific identification method.

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STAAR SURGICAL COMPANY AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Inventories

Inventories are stated at the lower of cost, determined on a first-in, first-out basis, or market. Inventory costs are comprised of material, direct labor, and overhead. The Company records inventory provisions, based on a review of forecasted demand and inventory levels.

Property, Plant and Equipment

Property, plant and equipment are recorded at cost. Depreciation on property, plant, and equipment is computed using the straight-line method over the estimated useful lives of the assets, generally ranging from 3 to 10 years. Major improvements are capitalized and minor replacements, maintenance and repairs are charged to expense as incurred.

Demonstration Equipment

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

Goodwill and Other Intangible Assets

Goodwill represents the excess of the purchase price over the fair value of identifiable net assets acquired in business combinations accounted for as purchases. The Company adopted Statement of Financial Accounting Standards (SFAS) No. 141, Business Combinations, and No. 142, Goodwill and Other Intangible Assets, on December 29, 2001.

Goodwill, which has an indefinite life and was previously amortized on a straight-line basis over the periods benefited, is no longer amortized to earnings but instead is subject to periodic testing for impairment. Intangible assets determined to have definite lives are amortized over their remaining useful lives. Goodwill of a reporting unit is tested for impairment on an annual basis or between annual tests if an event occurs or circumstances change that would reduce the fair value of a reporting unit below its carrying amount. As provided under SFAS No. 142, an annual assessment was completed during fiscal year 2004 and no impairment was identified. As of December 31, 2004, the carrying value of goodwill was $7.5 million.

The Company also has other intangible assets consisting of patents and licenses, with a gross book value of $11.5 million and accumulated amortization of $6.1 million as of December 31, 2004. The Company capitalizes the costs of acquiring patents and licenses. Amortization is computed on the straight-line basis over the estimated useful lives, which are based on legal and contractual provisions, and range from 10 to 20 years. Aggregate amortization expense for amortized other intangible assets was $688,000, $952,000 and $933,000 for the years ended December 31, 2004, January 2, 2004 and January 3, 2003, respectively.

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STAAR SURGICAL COMPANY AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The following table shows the estimated amortization expense for these assets for each of the five succeeding years (in thousands):

Fiscal Year	
2005	$ 481
2006	479
2007	479
2008	479
2009	478
Total	$ 2,396

Impairment of Long-Lived Assets

In accordance with SFAS No. 144, Accounting for the Impairment of Long-Lived Assets, intangible and other long lived-assets are reviewed for impairment whenever events such as product discontinuance, plant closures, product dispositions or other changes in circumstances indicate that the carrying amount may not be recoverable. In reviewing for impairment, the Company compares the carrying value of such assets to the estimated undiscounted future cash flows expected from the use of the assets and their eventual disposition. When the estimated undiscounted future cash flows are less than their carrying amount, an impairment loss is recognized equal to the difference between the assets fair value and their carrying value.

During the year ended January 2, 2004, the Company wrote down $2.1 million (net book value) in capitalized patent costs in connection with its routine evaluation of patent costs. The write-down related to patents acquired in the purchase of its majority interest in Circuit Tree Medical, a developer and manufacturer of phacoemulsification equipment, whose ongoing operations were moved to the Company s Monrovia, CA facility during the quarter. The Company believes the write-down was necessary based upon the subsidiary s historical losses and management s uncertainty about whether the Company will be able to recover the cost. There were no impairments of long-lived assets identified during the year ended December 31, 2004.

Accounting Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the amounts reported in the financial statements and footnotes thereto. Actual results may materially differ from those estimates.

Fair Value of Financial Instruments

The carrying values reflected in the consolidated balance sheets for cash and cash equivalents, accounts receivable, accounts payable, and notes payable approximate their fair values because of the short maturity of these instruments.

Loss Per Share

The Company presents loss per share data in accordance with the provision of SFAS No. 128, Earnings per Share, which provides for the calculation of basic and diluted earnings per share. Loss per share of common stock is computed by using the weighted average number of common shares outstanding during the period. Common stock equivalents are not included in the determination of the weighted average number of shares outstanding, as they would be antidilutive. For the years ended December 31, 2004, January 2, 2004, and January 3, 2003, 3.1 million, 3.2 million, and 3.1 million options to purchase shares of the Company s common stock, respectively, were excluded from the computation.

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STAAR SURGICAL COMPANY AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Stock Based Compensation

The Company accounts for stock-based compensation in accordance with Accounting Principles Board (APB) Opinion No. 25, Accounting for Stock Issued to Employees (APB 25), and has adopted the disclosure provisions of SFAS No. 123, Accounting for Stock Based Compensation (SFAS 123). SFAS 123 defines a fair value based method of accounting for an employee stock option or similar equity instrument and encourages all entities to adopt that method of accounting for all of their employee stock compensation plans. However, it also allows an entity to continue to measure compensation cost for those plans using the intrinsic value based method of accounting prescribed by APB 25. If the APB 25 intrinsic value method of accounting is used, SFAS 123 requires pro forma disclosures of net income and earnings per share as if the fair value based method of accounting for stock based compensation had been applied. The Company records expense in an amount equal to the excess of the quoted market price on the grant date over the option price. Such expense is recognized at the grant date for options fully vested. For options with a vesting period, the expense is recognized over the vesting period.

SFAS 123, Accounting for Stock-Based Compensation requires the Company to provide pro forma information regarding net income and earnings per share as if compensation expense for the Company s stock option plans had been determined in accordance with the fair value based method. The fair value of each stock option grant is estimated on the grant date using the Black-Scholes option-pricing model with the following assumptions:

	2004	2003	2002
Dividend yield	0%	0%	0%
Expected volatility	72%	69%	66%
Risk-free interest rate	4.22%	4.37%	4.50%
Expected holding period (in years)	4.2	4.8	5.4

The weighted average fair value of options granted during the year ended December 31, 2004, January 2, 2004 and January 3, 2003 was $2.14 to $4.55, $1.91 to $7.10 and $1.27 to $2.44, respectively.

Pro forma net loss and loss per share for fiscal years 2004, 2003 and 2002, had the Company accounted for stock options issued to employees and others in accordance with the fair value method of SFAS 123, are as follows (in thousands, except per share data):

	2004	2003	2002
Net loss			
As reported	$ (11,332)	$ (8,357)	$ (16,778)
Add: Stock-based employee compensation expense included in reported net loss			
Deduct: Total stock-based employee compensation expense determined under fair value based method for all awards	(739)	(1,563)	(1,679)
Pro forma	$ (12,071)	$ (9,920)	$ (18,457)
Basic and diluted loss per share			
As reported	$ (0.58)	$ (0.47)	$ (0.98)
Pro forma	$ (0.62)	$ (0.56)	$ (1.08)

Comprehensive Loss

The Company presents comprehensive losses in its Consolidated Statement of Changes in Stockholders Equity in accordance with SFAS No. 130, Reporting Comprehensive Income (SFAS 130). Total comprehensive loss includes, in addition to net loss, changes in equity that are excluded from the consolidated

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STAAR SURGICAL COMPANY AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

statements of operations and are recorded directly into a separate section of stockholders equity on the consolidated balance sheets.

Comprehensive loss and its components consist of the following (in thousands):

	2004	2003	2002
Net loss	$ (11,332)	$ (8,357)	$ (16,778)
Foreign currency translation adjustment	452	683	1,617
Comprehensive loss	$ (10,880)	$ (7,674)	$ (15,161)

Segments of an Enterprise

The Company reports segment information in accordance with SFAS No. 131, Disclosures about Segments of an Enterprise and Related Information (SFAS 131). Under SFAS 131 all publicly traded companies are required to report certain information about the operating segments, products, services and geographical areas in which they operate and their major customers. While the Company has expanded its marketing focus beyond the cataract market to include the refractive and glaucoma markets, the cataract market remains its primary source of revenues and, accordingly, the Company operates as one business segment (Note 17).

Research and Development Costs

Expenditures for research activities relating to product development and improvement are charged to expense as incurred.

Reclassifications

Certain reclassifications have been made to the prior year consolidated financial statements to conform to the 2004 presentation.

New Accounting Pronouncements

In October 2004, the American Jobs Creation Act of 2004 (Act) became effective in the U.S. Two provisions of the Act may impact the Company s provision (benefit) for income taxes in future periods, namely those related to the qualified production activities deduction (QPA) and foreign earnings repatriation (FER).

The QPA will be effective for the Company s U.S. federal tax return year beginning after December 31, 2004. In summary, the Act provides for a percentage deduction of earnings from qualified production activities, as defined, commencing with an initial deduction of 3 percent for tax years beginning after 2009, with the result that the statutory federal tax rate currently applicable to the Company s qualified production activities of 35 percent could be reduced initially to 33.95 percent and ultimately to 31.85 percent. However, the Act also provides for the phased elimination of the extraterritorial income exclusion provision of the Internal Revenue Code, which have previously resulted in tax benefits to the Company. Due to the interaction of the law provisions noted above as well as the particulars of the Company s tax position, the ultimate effect of the QPA on the Company s future provision (benefit) for income taxes has not been determined at this time. The Financial Accounting Standards Board (FASB) issued FASB Staff Position FAS 109-1, Application of FASB Statement No. 109, Accounting for Income Taxes, to the Tax Deduction on Qualified Production Activities Provided by the American Jobs Creation Act of 2004 (FSP 109-1), in December 2004. FSP 109-1 requires that tax benefits resulting from the QPA should be recognized no earlier than the year in which they are reported in the entity s tax return, and that there is to be no revaluation of recorded deferred tax assets and liabilities as would be the case had there been a change in an applicable statutory rate.

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STAAR SURGICAL COMPANY AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The FER provision of the Act provides generally for a one-time 85 percent dividends received deduction for qualifying repatriations of foreign earnings to the U.S. Qualified repatriated funds must be reinvested in the U.S. in certain qualifying activities and expenditures, as defined by the Act. In December 2004, the FASB issued FASB Staff Position FAS 109-2, Accounting and Disclosure Guidance for the Foreign Earnings Repatriation Provision within the American Jobs Creation Act of 2004 (FSP 109-2). FSP 109-2 allows additional time for entities potentially impacted by the FER provision to determine whether any foreign earnings will be repatriated under this provision. At this time, the Company has not undertaken an evaluation of the application of the FER provision and any potential benefits of effecting such repatriations under this provision. Numerous factors, including previous actual and deemed repatriations under federal tax law provisions, are factors impacting the availability of the FER provision to the Company and its potential benefit to the Company, if any. The Company intends to examine the issue and will provide updates in subsequent periods.

In November 2004, the FASB issued Statement of Financial Accounting Standards (SFAS) No. 151, Inventory Costs. This statement amends the guidance in ARB No. 43, Chapter 4, Inventory Pricing, to clarify the accounting for abnormal amounts of idle facility expense, freight, handling costs, and wasted materials (spoilage). SFAS No. 151 requires that those items be recognized as current-period charges. In addition, this statement requires that allocation of fixed production overheads to costs of conversions be based upon the normal capacity of the production facilities. The provisions of SFAS No. 151 are effective for inventory cost incurred in fiscal years beginning after June 15, 2005. As such, the Company is required to adopt these provisions at the beginning of fiscal 2006. The adoption of this pronouncement is not expected to have a material effect on the Company s financial statements.

In December 2004, the FASB issued SFAS No. 123R, Share-Based Payment. This statement is a revision of SFAS No. 123, Accounting for Stock-Based Compensation, and supersedes APB Opinion No. 25, Accounting for Stock Issued to Employees, and its related implementation guidance. SFAS No. 123R addresses all forms of share-based payment (SBP) awards including shares issued under employee stock purchase plans, stock options, restricted stock and stock appreciation rights. Under SFAS No. 123R, SBP awards result in a cost that will be measured at fair value on the awards grant date, based on the estimated number of awards that are expected to vest. This statement is effective for public entities as of the beginning of the next fiscal year that begins after June 15, 2005. The Company has not quantified the potential effect of adoption of SFAS No. 123R, but believes that the adoption of this statement will result in a decrease to earnings.

In December 2004, the FASB issued SFAS No. 153, Exchange of Nonmonetary Assets. This statement amends Opinion 29 to eliminate the exception for nonmonetary exchanges of similar productive assets and replaces it with a general exception for exchanges of nonmonetary assets that do not have commercial substance. A nonmonetary exchange has commercial substance if the future cash flows of the entity are expected to change significantly as a result of the exchange. The provisions of this statement are effective for nonmonetary asset exchanges occurring in fiscal periods beginning after June 15, 2005. Earlier application is permitted for nonmonetary asset exchanges occurring in fiscal periods beginning after December 16, 2004. The provisions of this statement should be applied prospectively. The adoption of this pronouncement is not expected to have a material effect on the Company s financial statements.

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STAAR SURGICAL COMPANY AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 2 Short-Term Investments

Short-term investments consisted of the following at December 31, 2004 and January 2, 2004 (in thousands):

	2004		2003	
	Cost	Market Value	Cost	Market Value
Auction rate securities	$ 5,125	$ 5,125		
	$ 5,125	$ 5,125	$	$

The short-term investments are comprised solely of taxable auction-rate securities within a closed-end fund with no stated maturity date. Due to the fact that these investments have frequent interest rate resets, the Company did not have any gross unrealized gains or losses at December 31, 2004 or January 2, 2004. The Company classifies the securities as available for sale investments.

Note 3 Accounts Receivable

Accounts receivable consisted of the following at December 31, 2004 and January 2, 2004 (in thousands):

	2004	2003
Domestic	$ 2,602	$ 2,834
Foreign	4,075	3,575
	6,677	6,409
Less allowance for doubtful accounts and sales returns	460	734
	$ 6,217	$ 5,675

Note 4 Inventories

Inventories consisted of the following at December 31, 2004 and January 2, 2004 (in thousands):

	2004	2003
Raw materials and purchased parts	$ 985	$ 830
Work in process	2,253	1,273
Finished goods	11,846	10,699
	$ 15,084	$ 12,802

Note 5 Property, Plant and Equipment

Property, plant and equipment consisted of the following at December 31, 2004 and January 2, 2004 (in thousands):

	2004	2003
Machinery and equipment	$ 12,388	$ 12,791
Furniture and fixtures	4,378	3,808
Leasehold improvements	4,826	4,608
	21,592	21,207
Less accumulated depreciation and amortization	15,429	14,569
	$ 6,163	$ 6,638

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STAAR SURGICAL COMPANY AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Depreciation expense for the years ended December 31, 2004, January 2, 2004, and January 3, 2003 was $2.0 million, $2.0 million and $2.2 million, respectively.

Note 6 Investment in Joint Venture

The Company owns a 50% equity interest in a joint venture, the Canon Staar Co., Inc. (CSC), with Canon Inc. and Canon Sales Co, Inc., together the Canon Companies (see Note 1). The investment in the Japanese joint venture is accounted for using the equity method of accounting except for the nine months ended September 29, 2001 when income was recorded on a cash basis due to disputes between the Company and the Canon Companies which were resolved during the fourth quarter of 2001. Dividends received, relating to periods when the Company accounted for its investment on a cash basis, were charged to earnings on a cash basis. For all other periods, dividends are recorded under the equity method as a reduction to the investment.

The financial statements of CSC include the following information:

	2004	2003
Current assets	$ 6,237	$ 7,728
Non-current assets	1,402	3,297
Current liabilities	1,238	1,881
Non-current liabilities	807	829
Net sales	10,908	9,273
Gross profit	4,572	3,237
Income from operations	6,163	122
Net loss	$ (304)	$ 22

The Company s equity in earnings (loss) of the joint venture is calculated as follows (in thousands):

	2004	2003	2002
Joint venture net income (loss)	$ (382)	$ 22	$ (8)
Equity interest	50%	50%	50%
Total joint venture net income (loss)	(191)	11	(4)
Cash basis dividends			40
Equity in earnings (loss) of joint venture	$ (191)	$ 11	$ 36

The Company received dividends of $81,000, $76,000 and $40,000 during 2004, 2003 and 2002, respectively.

The Company recorded sales of certain IOL products to CSC of approximately $185,000, $66,000 and $142,000 in 2004, 2003 and 2002, respectively.

The Company purchased preloaded injectors from CSC in the amount of $1.7 million, $239,000, and $0 in 2004, 2003, and 2002, respectively.

Note 7 Notes Payable

The Company had a $7 million line of credit with a domestic lender which was amended and restated from time to time during fiscal 2003 and 2002. The Company s obligation to the lender was secured by a first priority lien on substantially all of the Company s assets and included certain financial covenants. The note carried an interest rate equal to the prime rate (4.25% at January 3, 2003), plus interest margin and commitment fees of 5% and 1.25% per

annum, respectively. Borrowings outstanding under the note as of January 3, 2003 were approximately $2.9 million, with total borrowings of up to $3.7 million available under

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STAAR SURGICAL COMPANY AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

the line of credit. During 2003, the note, which was originally due March 31, 2003, was extended one year to March 31, 2004. In June 2003, the Company paid off the note and canceled the line of credit.

Subsidiaries of the Company have foreign credit facilities with different banks to support operations in Switzerland and Germany.

The Swiss credit agreement, as amended on August 2, 2004, provides for borrowings of up to 3.75 million Swiss Francs CHF (approximately $3.3 million based on the rate of exchange on December 31, 2004), and permits either fixed-term or current advances. The interest rate on current advances is 6.0% per annum at December 31, 2004 and January 2, 2004, respectively, plus a commission rate of 0.25% payable quarterly. There were no current advances outstanding at December 31, 2004 or January 2, 2004. The base interest rate for fixed-term advances follows Euromarket conditions for loans of a corresponding term and currency, plus an individual margin (4.5% at December 31, 2004 and 4.2% at January 2, 2004). Borrowings outstanding under the facility were CHF 3.4 million at December 31, 2004 (approximately $3.0 million based on the rate of exchange at December 31, 2004) and CHF 3.7 million at January 2, 2004 (approximately $3.0 million based on the rate of exchange on January 2, 2004). The credit facility is secured by a general assignment of claims and includes positive and negative covenants which, among other things, require the maintenance of a minimum level of equity of at least $12.0 million and prevents the Swiss subsidiary from entering into other secured obligations or guaranteeing the obligations of others. The agreement also prohibits the sale or transfer of patents or licenses without the prior consent of the lender and the terms of intercompany receivables may not exceed 90 days.

The Swiss credit facility is divided into two parts. Part A provides for borrowings of up to CHF 3.0 million ($2.7 million based on the exchange rate on December 31, 2004) and does not have a termination date. Part B presently provides for borrowings of up to CHF 750,000 ($662,000 based on the exchange rate on December 31, 2004). The loan amount under Part B of the agreement reduces by CHF 250,000 ($220,000 based on the exchange rate on December 31, 2004) semi-annually.

The German credit agreement, entered into during fiscal year 2003, provides for borrowings of up to 210,000 EUR ($286,000 based on the exchange rate on December 31, 2004), at a rate of 8.5% per annum and renews automatically each November. The agreement prohibits our German subsidiary from paying dividends and is personally guaranteed by the president of the subsidiary. There were no borrowings outstanding as of December 31, 2004 or January 2, 2004.

The Company was in compliance with the covenants of credit facilities as of December 31, 2004.

Note 8 Income Taxes

The provision (benefit) for income taxes consists of the following (in thousands):

	2004	2003	2002
Current tax provision (benefit):			
U.S. federal	$	$	$ (995)
State			(74)
Foreign	1,057	1,127	742
Total current provision (benefit)	1,057	1,127	(327)
Deferred tax provision (benefit):			
U.S. federal and state			9,021
Foreign			111
Total deferred provision (benefit)			9,132

Provision (benefit) for income taxes	$ 1,057	$ 1,127	$ 8,805

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STAAR SURGICAL COMPANY AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Legislation enacted on March 9, 2002 (HR 3090) enabled the Company to carryback a portion of the federal 2001 net operating loss to 1996, 1997 and 1998. Since this legislation was not enacted as of the end of fiscal year 2001, the benefit of $959,000 from this carryback was recorded in 2002. As of December 31, 2004, the Company had $63.6 million of federal net operating loss carryforwards available to reduce future income taxes. The net operating loss carryforwards expire in varying amounts between 2020 and 2024.

The Company has net income taxes payable at December 31, 2004 and January 2, 2004 of $420,000 and $416,000, respectively.

The provision (benefit) for income before taxes differs from the amount computed by applying the statutory federal income tax rate to income before taxes as follows (in thousands):

	2004		2003		2002	
Computed provision for taxes based on income at statutory rate	$ (3,484)	34.0%	$ (2,435)	34.0%	$ (2,685)	34.0%
Increase (decrease) in taxes resulting from:						
Write down of investment in Circuit Tree Medical Inc.			715	(10.0)		
Permanent differences	36	(0.3)	23	(0.3)	38	(0.5)
State taxes, net of federal income tax benefit		(0.0)		(0.0)	1,305	(16.5)
Tax effect attributed to foreign operations	158	(1.5)	107	(1.5)	(1,245)	15.8
Other	7	(0.1)				
Valuation allowance	4,340	(42.4)	2,717	(37.9)	11,392	(144.3)
Effective tax provision (benefit) rate	$ 1,057	(10.3)%	$ 1,127	(15.7)%	$ 8,805	(111.5)%

Undistributed earnings of the Company s foreign subsidiaries amounted to approximately $12.1 million at December 31, 2004. Undistributed earnings are considered to be indefinitely reinvested and, accordingly, no provision for United States federal and state income taxes has been provided thereon. Upon distribution of earnings in the form of dividends or otherwise, the Company would be subject to both United States income taxes (subject to an adjustment for foreign tax credits) and withholding taxes payable to the various foreign countries. Determination of the amount of unrecognized deferred United States income tax liability is not practicable because of the complexities associated with its hypothetical calculation.

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STAAR SURGICAL COMPANY AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of the Company s deferred tax assets (liabilities) as of December 31, 2004 and January 2, 2004 are as follows (in thousands):

	2004	2003
Current deferred tax assets (liabilities):		
Allowance for doubtful accounts and sales returns	$ 143	$ 114
Inventory	475	611
Accrued vacation	171	156
State taxes	3	3
Deferred revenue	79	6
Accrued expenses	21	
Valuation allowance	(892)	(890)
Total current deferred tax assets (liabilities)	$	$
Non-current deferred tax assets (liabilities):		
Net operating loss and capital loss carryforwards	25,508	19,141
Business, foreign and AMT credit carryforwards	880	876
Depreciation and amortization	(54)	194
Notes receivable	207	
Reserve for restructuring costs	450	429
Subpart F income		267
Capitalized R&D	252	246
Contributions	37	32
Valuation allowance	(27,280)	(21,185)
Total non-current deferred tax assets (liabilities)	$	$

SFAS No. 109, Accounting for Income Taxes (SFAS 109) requires that a valuation allowance be established when it is more likely than not that all or a portion of a deferred tax asset may not be realized. Cumulative losses weigh heavily in the assessment of the need for a valuation allowance. In 2002, due to the Company s recent history of losses, an increase to the valuation allowance was recorded as a non-cash charge to tax expense in the amount of $9.0 million. As a result, the valuation allowance fully offsets the value of deferred tax assets on the Company s balance sheet as of December 31, 2004. Under Section 382 of the Internal Revenue Code, significant changes in ownership may restrict the future utilization of these tax loss carry forwards.

In 1995, a subsidiary of the Company obtained retrospectively to 1993, a ten-year tax holiday for the payment of federal, cantonal and municipal income taxes in Switzerland. As such, Swiss income taxes were not due on the operations of this subsidiary for the ten year period that ended on December 31, 2002. As the tax holiday from Swiss taxes has expired, the appropriate federal, cantonal and municipal income taxes have been included in the foreign tax provision.

Income (loss) before income taxes are as follows (in thousands):

	2004	2003	2002

Domestic	$ (12,887)	$ (10,163)	$ (14,066)
Foreign	2,641	3,001	6,168
	$ (10,246)	$ (7,162)	$ (7,898)

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STAAR SURGICAL COMPANY AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 9 Business Acquisitions

During the year ended December 31, 2004, the Company purchased the remaining 20% interest in its Australian subsidiary for $1.3 million, in exchange for $768,000 in cash and a long-term note in the amount of $542,000 due on November 1, 2007. The transaction resulted in the recording of goodwill of $1.1 million. The Company also entered into employment agreements with the previous minority owners of the subsidiary. The employment agreements expire on November 1, 2007 and include clauses to not compete for a period of one year after termination for any cause, except in the event of a change in control.

Pro forma amounts for the acquisition are not included, as the effect on operations is not material to the Company s consolidated financial statements.

During the year ended January 3, 2003, the Company acquired the remaining 20% interest in its German subsidiary at its book value of $426,000, from the subsidiary s president in exchange for cancellation of amounts due from the subsidiary s president of $955,000 less bonuses due to the subsidiary s president of $87,000, resulting in goodwill of $442,000. The terms of the agreement also provided for the cancellation of 75,000 unexercised stock options previously issued to the subsidiary s president and an agreement not to compete with the Company for a period of ten years.

Pro forma amounts for the acquisition are not included, as the effect on operations is not material to the Company s consolidated financial statements.

Note 10 Stockholders Equity

Common Stock

During fiscal year 2004, the Company issued 11,000 shares to consultants for services rendered to the Company. Also during 2004, the Company completed a private placement with institutional investors of 2 million shares of the Company s common stock, for net proceeds of $11.6 million.

During fiscal year 2003, the Company issued 11,000 shares to consultants for services rendered to the Company and 43,000 shares, in lieu of bonuses earned, to an officer and director of the Company. Also during 2003, the Company completed a private placement with institutional investors of 1 million shares of the Company s common stock, for net proceeds of $8.9 million.

During fiscal year 2002, the Company issued 39,000 shares to consultants for services rendered to the Company and 3,000 shares to an employee relating to an employment contract. Also during 2002, the Company acquired 243,000 shares of treasury stock from a former officer in settlement of notes receivable.

Receivables from Officers and Directors

As of December 31, 2004 and January 2, 2004, notes receivable (excluding reserves) from former officers and directors totaling $2.1 million and $2.3 million, respectively, were outstanding. The notes were issued in connection with purchases of the Company s common stock and bear interest at rates ranging between 1.98% and 6.40% per annum, or at the lowest federal applicable rate allowed by the Internal Revenue Service. The notes are secured by stock pledge agreements and other assets and mature on various dates through June 1, 2006.

During the year ended December 31, 2004, the Company entered into a forbearance agreement with a former director of the Company whereby the due date of the $1.2 million note receivable was extended from June 15, 2004 to March 15, 2005 and the interest rate was reduced to 1.986%, which was the lowest applicable federal rate at the date of the agreement.

During the year ended December 31, 2004, the Company recorded a $500,000 reserve against the notes of a former director of the Company which total $1.8 million including accrued interest. The notes are

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STAAR SURGICAL COMPANY AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

collateralized by the Company s common stock and a second mortgage on a home in Florida. The current value of the collateral is approximately $1.3 million. The amount of the reserve is based on the difference between the note amount and the collateral value.

During the year ended January 3, 2003, the Company entered into a promissory note in the amount of $560,000 pursuant to the terms of a settlement agreement with a law firm, of which a principal was a former officer, director and stockholder of the Company. Terms of the note, secured by trade accounts receivable of the law firm, include interest at the rate of 5% with monthly payment of principal and interest due beginning July 1, 2002 through June 1, 2006. During the years ended December 31, 2004 and January 2, 2004, payments against the note were received in the amount of $180,000 and $100,000, respectively.

Also during the year ended January 3, 2003, the Company entered into a second promissory note in the amount of $2.2 million, pursuant to the terms of the same settlement agreement, with the former officer s widow. Terms of the note, secured by a stock pledge agreement, included interest at the rate of 5% with principal and interest due on or before March 29, 2006. The note also provided for escalation in the interest rate to 9.75% if the bid price of the Company s common stock traded at $8.00 or greater on any public stock exchange for a period of 20 consecutive trading days, or if the stock permanently ceased to trade on any public stock exchange. Additionally, the note provided an acceleration of payment in the event the closing bid price of the common stock of the Company traded at $10.00 or greater on any public stock exchange for a period of 20 consecutive trading days. The note was paid in full in July 2003.

Options

The table below summarizes the transactions in the Company s stock option plans (in thousands except per share data):

	Number of Shares	Weighted Average Exercise Price
Balance at December 28, 2001	2,911	$ 8.85
Options granted	972	$ 3.73
Options exercised		$
Options forfeited/ cancelled	(746)	$ 10.55
Balance at January 3, 2003	3,137	$ 6.86
Options granted	553	$ 4.52
Options exercised	(387)	$ 4.03
Options forfeited/ cancelled	(84)	$ 5.89
Balance at January 2, 2004	3,219	$ 6.84
Options granted	531	$ 7.76
Options exercised	(250)	$ 3.32
Options forfeited/ cancelled	(348)	$ 8.27
Balance at December 31, 2004	3,152	$ 7.12
Options exercisable (vested) at December 31, 2004	2,535	$ 7.27

In fiscal year 2003, the Board of Directors approved the 2003 Omnibus Equity Incentive Plan (the 2003 Plan) authorizing the granting of options to purchase or awards of the Company s common stock. The 2003 Plan amends, restates and replaces the 1991 Stock Option Plan, the 1995 Consultant Stock Plan, the 1996 Non-Qualified Stock Plan and the 1998 Stock Option Plan (the Restated Plans). Under provisions of the 2003 Plan, all of the unissued shares in the Restated Plans are reserved for issuance in the 2003 Plan. In addition, 2% of the total shares of common stock outstanding on the immediately preceding December 31 will be reserved for issuance under the 2003 Plan. Options under the plan are granted at fair market value on the

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STAAR SURGICAL COMPANY AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

date of grant, become exercisable over a 3-year period, or as determined by the Board of Directors, and expire over periods not exceeding 10 years from the date of grant. Pursuant to the plan, options for 522,000 and 83,000 shares were outstanding at December 31, 2004 and January 2, 2004, respectively, with exercise prices ranging between $3.00 and $11.24 per share.

In fiscal year 2000, the Board of Directors approved the Stock Option Plan and Agreement for the Company s Chief Executive Officer authorizing the granting of options to purchase or awards of the Company s common stock. The options under the plan are granted at fair market value on the date of grant, become exercisable over a 3-year period, and expire 10 years from the date of grant. Pursuant to this plan, options for 500,000 were outstanding at December 31, 2004, January 2, 2004, and January 3, 2003, respectively, with an exercise price of $11.125.

In fiscal year 1998, the Board of Directors approved the 1998 Stock Option Plan, authorizing the granting of incentive options and/or non-qualified options to purchase or awards of the Company s common stock. Under the provisions of the plan, 1.0 million shares were reserved for issuance; however, the maximum number of shares authorized may be increased provided such action is in compliance with Article IV of the plan. During fiscal year 2001, pursuant to Article IV of the plan, the stockholders of the Company authorized an additional 1.5 million shares. Generally, options under the plan are granted at fair market value at the date of the grant, become exercisable over a 3-year period, or as determined by the Board of Directors, and expire over periods not exceeding 10 years from the date of grant. Pursuant to the plan, options for 1.6 million, 1.9 million and 1.5 million shares were outstanding at December 31, 2004, January 2, 2004, and January 3, 2003, respectively, with exercise prices ranging between $2.00 and $13.875 per share.

In fiscal year 1996, the Board of Directors approved the 1996 Non-Qualified Stock Plan, authorizing the granting of options to purchase or awards of the Company s common stock. Under provisions of the Non-Qualified Stock Plan, 600,000 shares were reserved for issuance. Generally, options under the plan are granted at fair market value at the date of the grant, become exercisable over a 3-year period, or as determined by the Board of Directors, and expire over periods not exceeding 10 years from the date of grant. Pursuant to this plan, options for 146,000, 146,000, and 170,000 shares were outstanding at December 31, 2004, January 2, 2004, and January 3, 2003, respectively. The options were originally issued with an exercise price of $12.50 per share. During fiscal year 1998 the exercise price was reduced to $6.25 per share by action of the Board of Directors.

In fiscal year 1995, the Company adopted the 1995 Consultant Stock Plan, authorizing the granting of options to purchase or awards of the Company s common stock. Generally, options under the plan are granted at fair market value at the date of the grant, become exercisable on the date of grant and expire 10 years from the date of grant. Pursuant to this plan, options for 165,000, 330,000, and 545,000 shares were outstanding at December 31, 2004, January 2, 2004, and January 3, 2003, respectively, with exercise prices ranging from $1.70 to $3.99 per share.

Under provisions of the Company s 1991 Stock Option Plan, 2.0 million shares were reserved for issuance. Generally, options under this plan are granted at fair market value at the date of the grant, become exercisable over a 3-year period, or as determined by the Board of Directors, and expire over periods not exceeding 10 years from the date of grant. At December 31, 2004, January 2, 2004, and January 3, 2003, options for 163,000, 220,000, and 379,000 shares were outstanding, with exercise prices ranging from $9.56 to $11.25 per share.

In fiscal year 2004, officers, employees and others exercised 250,000 options from the 1995, 1998 and 2003 stock option plans at prices ranging from $1.90 to $4.65 resulting in cash proceeds totaling $829,000.

In fiscal year 2003, officers, employees and others exercised 387,000 options from the 1991, 1996 and 1998 stock option plans at prices ranging from $2.00 to $9.56 resulting in cash proceeds totaling $1.6 million.

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STAAR SURGICAL COMPANY AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

In fiscal year 2002, no options were exercised from any of the Company s stock option plans.

The following table summarizes information about stock options outstanding and exercisable at December 31, 2004 (in thousands, except per share data):

Range of Exercise Prices	Options Outstanding Number Outstanding at 12/31/04	Options Outstanding Weighted-Average Remaining Contractual Life	Options Outstanding Weighted-Average Exercise Price	Options Exercisable Number Exercisable at 12/31/04	Options Exercisable Weighted-Average Exercise Price
	(In thousands)			(In thousands)	
$ 1.70 to $ 2.15	160	3.1 years	$ 1.93	160	$ 1.93
$ 2.96 to $ 4.30	1,037	4.1 years	$ 3.54	821	$ 3.52
$ 4.62 to $ 6.25	402	0.8 years	$ 5.61	365	$ 5.64
$ 7.00 to $10.19	620	6.2 years	$ 8.75	314	$ 9.67
$10.60 to $13.88	933	3.9 years	$ 11.54	875	$ 11.58
$ 1.70 to $13.88	3,152	4.0 years	$ 7.12	2,535	$ 7.27

Note 11 Commitments and Contingencies

Lease Obligations

The Company leases certain property, plant and equipment under capital and operating lease agreements. These leases vary in duration and many contain renewal options and/or escalation clauses.

Estimated future minimum lease payments under leases having initial or remaining non-cancelable lease terms in excess of one year as of December 31, 2004 were approximately as follows (in thousands):

Fiscal Year	Operating Leases	Capital Leases
2005	$ 927	$ 92
2006	435	6
2007	435	3
2008	437	2
2009	52	2
Total minimum lease payments	$ 2,286	$ 105
Less amounts representing interest		(8)
	$ 2,286	$ 97
Current		$ 86
Long-term		11

Total	$ 97

Rent expense was approximately $1.2 million, $1.2 million, and $1.1 million for each of the years ended December 31, 2004, January 2, 2004 and January 3, 2003, respectively.

Supply Agreement

In May 1999, the Company entered into a license and supply agreement with another manufacturer to license and re-sell one of the manufacturer s products. Under the terms of the agreement, the Company was committed to purchase the specified product for a total sum of $3.2 million over 18 months. In September 2001, the supply agreement was amended reducing the minimum contractual amount that the Company is

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STAAR SURGICAL COMPANY AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

obligated to purchase from the manufacturer to $2.5 million over a 24-month period commencing September 1, 2001. The agreement, which was cancelable upon four months written notice, was terminated during the quarter ended January 2, 2004 at no additional expense. Purchases under the agreement for fiscal 2004 and 2003 were approximately $0 and $954,000, respectively.

In December 2000, the Company entered into a minimum purchase agreement with another manufacturer for the purchase of viscoelastic solution. In addition to the minimum purchase requirement, the Company is also obligated to pay an annual regulatory maintenance fee. The agreement contains provisions to increase the minimum annual purchases in the event that the seller gains regulatory approval of the product in other markets, as requested by the Company. Purchases under the agreement for fiscal 2004 and 2003 were approximately $644,000 and $568,000, respectively.

As of December 31, 2004, estimated annual purchase commitments under these contracts are as follows (in thousands):

Fiscal Year	
2005	$ 1,022
2006	200
Total	$ 1,222

FDA Warning Letters and 483 Observations

The Company received a Warning Letter issued by the FDA, dated December 22, 2003 which outlined deficiencies related to the manufacturing and quality assurance systems of its Monrovia, California facility. To assist it in correcting the issues raised in the Warning Letter, the Company engaged the services of Quintiles Consulting (Quintiles), a well regarded consulting organization that specializes in FDA related compliance matters. The Company, with Quintiles help, assessed the state of its quality system in light of the FDA s concerns, developed an improvement plan, and took corrective actions to improve the Company s processes, procedures, and controls.

The Company received a second Warning Letter from the FDA dated April 26, 2004, which outlined deficiencies noted in an audit by the FDA in December 2003. The Company provided the FDA with its planned corrective actions to the issues raised, and in a letter dated July 1, 2004, the FDA responded that they found the corrective and preventative action plans described in the Company s response adequate.

On June 17, 2004, the FDA completed an audit of the Company s Nidau, Switzerland manufacturing facility. The FDA did not observe any violations of Quality System and Good Manufacturing Practices requirements during this audit.

Costs associated with the preparation for these FDA inspections, and the improvements made to the quality assurance and regulatory compliance functions, contributed to the 22% increase in research and development expenses (which included regulatory and quality assurance expenses) for the year ended December 31, 2004, compared to fiscal 2003. Additionally, the Warning Letters and 483 Observations have affected the Company s reputation in the ophthalmic market and have adversely affected product sales for the year ended December 31, 2004.

Until the FDA is satisfied with the adequacy of the Company s corrective actions, it may take further actions which could include conducting another inspection, seizure of the Company s products, injunction of the Monrovia facility to compel compliance (which may include suspension of production operations and/or recall of products), or other actions. Such actions could have a material adverse effect on the Company s established lines of business, results of operations and liquidity. Furthermore, until the FDA is satisfied with the Company s response, it is unlikely to grant the Company approval to market the ICL in the United States.

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STAAR SURGICAL COMPANY AND SUBSIDIARIES
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The Company is not able to predict whether the FDA will conclude that the Company s corrective actions to date or those included in its response to the 483 Observations satisfactorily resolve its concerns. Nor can the Company predict the likelihood, nature of, or timing of any additional action by the FDA or the impact of other FDA action on the Company s established lines of business, results of the operations or liquidity or the approval of the ICL for the United States market.

Indemnification Agreements

The Company has entered into indemnification agreements with its directors and officers that may require the Company: to indemnify them against liabilities that may arise by reason of their status or service as directors or officers, except as prohibited by applicable law; to advance their expenses incurred as a result of any proceeding against them as to which they could be indemnified; and to make a good faith determination whether or not it is practicable for the Company to obtain directors and officers insurance. The Company currently has directors and officers insurance.

Litigation and Claims

Since September 1, 2004, multiple class action lawsuits have been filed in the United States District Courts for the Central District of California and the District of New Mexico against the Company and its Chief Executive Officer on behalf of all persons who acquired the Company s securities during various periods between April 3, 2003 and September 28, 2004. On December 15, 2004, the Court ordered consolidation of the complaints that had been filed in the United States District Court for the Central District of California and directed that the plaintiffs file a consolidated complaint as soon as practicable. The plaintiffs have proposed a stipulation pursuant to which they would file a consolidated amended complaint on or about April 29, 2005. The New Mexico action was voluntarily dismissed on January 28, 2005. The lawsuits generally allege that the defendants violated Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, as amended, and Rule 10b-5 promulgated thereunder, by issuing false and misleading statements regarding intraocular lenses and implantable lenses, and failing timely to disclose significant problems with the lenses, as well as the existence of serious injuries and/or malfunctions attributable to the lenses, thereby artificially inflating the price of the Company s Common Stock. The plaintiffs generally seek to recover compensatory damages, including interest. Although the Company intends to vigorously defend the consolidated lawsuit, the lawsuit will require significant attention of management and could result in substantial costs and harm our reputation.

The Company is currently party to various claims and legal proceedings arising out of the normal course of our business. These claims and legal proceedings relate to contractual rights and obligations, employment matters, and claims of product liability. While we do not believe that any of the claims known to us is likely to have a material adverse effect on our financial condition or results of operations, new claims or unexpected results of existing claims could lead to significant financial harm.

Note 12 Other Liabilities

Other Current Liabilities

Included in other current liabilities at December 31, 2004 and January 2, 2004 are approximately $1,868,000 and $1,534,000 of accrued salaries and wages and $808,000 and $959,000 of commissions due to outside sales representatives, respectively.

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STAAR SURGICAL COMPANY AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 13 Related Party Transactions

The Company has had significant related party transactions as discussed in Notes 6, 9 and 10.

The Company issues options to purchase 60,000 shares of its common stock at fair market value on the date of grant to each member of its Board of Directors upon election or reelection for services provided as Board members.

In addition to secured notes (see Note 10), the Company holds other various promissory notes from former officers and directors of the Company. The notes, which provide for interest at the lowest applicable rate allowed by the Internal Revenue Code, are due on demand. Amounts due from former officers and directors and included in prepaids, deposits, and other current assets at December 31, 2004 and January 2, 2004 were $104,000 and $98,000, respectively.

In March 2001, the Company entered into a consulting agreement with one of the members of its Board of Directors. In exchange for services, the Company issued an option to purchase 20,000 shares of the Company s common stock at fair market value on the date of grant, in addition to a monthly retainer of $6,000, and a per-diem rate after six days worked of $1,000. Upon the mutual consent of the parties, the agreement was cancelled in July 2003. However, the Company has continued to pay the Board member for consulting services. Amounts paid to during the year ended December 31, 2004, January 2, 2004, and January 3, 2003, were $13,000, $50,000, and $73,000, respectively.

Note 14 Supplemental Disclosure of Cash Flow Information

Interest paid was $159,000, $255,000 and $580,000 for the years ended December 31, 2004, January 2, 2004 and January 3, 2003, respectively. Income taxes paid amounted to approximately $1,602,000, $1,477,000 and $719,000 for the years ended December 31, 2004, January 2, 2004 and January 3, 2003, respectively. Income taxes paid in 2003 were partially offset by the receipt of $962,000 in U.S. federal tax refunds related to a carryback claim filed in 2002 (see Note 8).

The Company s non-cash investing and financing activities were as follows (in thousands):

	2004	2003	2002
Non-cash financing activities:			
Notes receivable from officers and directors (Note 8)	$	$	$ (2,129)
Notes receivable reserve	500	1,713	1,814
Prepaids, deposits and other current assets			(658)
Treasury stock acquired			973
Other charges	(500)	(1,713)	
Acquisition of business:			
Minority interest acquired	$ 203	$	$ 426
Goodwill	1,107		442
Note payable	(542)		(868)
Cash paid	(768)		
Patent impairment:			
Patents	$	$ (2,438)	$
Accumulated amortization		336	
Other charges		2,102	

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STAAR SURGICAL COMPANY AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 15 Other Charges

During the year ended December 31, 2004, the Company recorded a $500,000 reserve against the notes of a former director of the Company which total $1.8 million including accrued interest. The notes are collateralized by the Company s common stock and a second mortgage on a home in Florida. The current value of the collateral is approximately $1.3 million. The amount of the reserve is based on the difference between the note amount and the collateral value.

During 2003, the Company recorded $390,000 in other charges. The amount includes a charge of $2.1 million relating to the write-down of capitalized patent costs acquired in the purchase of the Company s majority interest in Circuit Tree Medical, a developer and manufacturer of phacoemulsification equipment, and was partially offset by the reversal of $1.7 million in reserves previously recorded against notes receivable from officers and directors which the Company has settled.

In connection with its business strategy to reduce operating expenses, announced during the third quarter of 2001, the Company completed the sale of its South African subsidiary and closure of its Swedish and Canadian subsidiaries during the year ended January 3, 2003. As a result of these transactions the Company recorded $1.2 million of subsidiary closure charges. The charges were primarily related to the recognition of deferred losses resulting from the translation of foreign currency statements into U.S. dollars (previously included in equity in the balance sheet in accordance with SFAS No. 52). Since the charges had been included in equity their subsequent recognition, while impacting retained earnings, had no impact on total stockholders equity.

Also included in other charges at January 3, 2003 is $230,000 in employee separation costs.

Note 16 Net Loss Per Share

The following is a reconciliation of the weighted average number of shares used to compute basic and diluted loss per share (in thousands):

	2004	2003	2002
Basic weighted average shares outstanding	19,602	17,704	17,142
Diluted effect of stock options and warrants			
Diluted weighted average shares outstanding	19,602	17,704	17,142

Note 17 Geographic and Product Data

The Company markets and sells its products in over 45 countries and has manufacturing sites in the United States and Switzerland. Other than the United States and Germany, the Company does not conduct business in any country in which its sales in that country exceed 5% of consolidated sales. Sales are attributed to countries based on location of customers. The composition of the Company s sales to unaffiliated customers between those in the United States, Germany, and other locations for each year, is set forth below (in thousands).

	2004	2003	2002
Sales to unaffiliated customers			
U.S.	$ 21,643	$ 23,464	$ 24,082
Germany	22,128	19,840	16,081
Other	7,914	7,105	7,717
Total	$ 51,685	$ 50,409	$ 47,880

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STAAR SURGICAL COMPANY AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The Company develops, manufactures and distributes medical devices used in minimally invasive ophthalmic surgery. Substantially, all of the Company s revenues result from the sale of the Company s medical devices. The Company distributes its medical devices in the cataract, refractive and glaucoma segments within ophthalmology. While the Company has expanded its marketing focus beyond the cataract market to include the refractive and glaucoma markets, the cataract market remains the Company s primary source of revenues and, therefore, the Company operates as one business segment for financial reporting purposes.

The cataract product line includes intraocular lenses, phacoemulsification equipment, viscoelastics, and other products used in cataract surgery. During the years presented, revenues from the refractive and glaucoma product lines were 9% or less of total revenue. Accordingly, the difference is not significant enough for the Company to account for these products separately and, therefore, those products are combined as other products in the following table.

Net Sales by Product Line

	2004	2003	2002
		(In thousands)	
Cataract	$ 46,772	$ 46,409	$ 44,349
Other	4,913	4,000	3,531
Total	$ 51,685	$ 50,409	$ 47,880

The composition of the Company s long-lived assets between those in the United States, Germany, Switzerland, and other countries is set forth below (in thousands).

	2004	2003
Long-lived assets		
U.S.	$ 9,035	$ 10,181
Germany	6,799	6,511
Switzerland	2,010	2,220
Other	1,253	212
Total	$ 19,097	$ 19,124

The Company sells its products internationally, which subjects the Company to several potential risks, including fluctuating exchange rates (to the extent the Company s transactions are not in U.S. dollars), regulation of fund transfers by foreign governments, United States and foreign export and import duties and tariffs, and political instability.

Note 18 Quarterly Financial Data (Unaudited)

Summary unaudited quarterly financial data from continuing operations for fiscal 2004 and 2003 is as follows (in thousands except per share data):

December 31, 2004	1st Qtr.	2nd Qtr.	3rd Qtr.	4th Qtr.
Revenues	$ 13,569	$ 12,024	$ 12,140	$ 13,952

Gross profit	7,317	6,150	6,097	6,579
Net loss	(1,299)	(3,380)	(2,268)	(4,385)
Basic and diluted loss per share	(.07)	(.18)	(.11)	(.21)

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STAAR SURGICAL COMPANY AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

January 2, 2004	1st. Qtr.	2nd Qtr.	3rd Qtr.	4th Qtr.
Revenues	$ 12,826	$ 12,951	$ 11,927	$ 12,754
Gross profit	6,979	7,056	6,587	7,215
Net loss	(958)	(1,169)	(2,710)	(3,520)
Basic and diluted loss per share	(.06)	(.07)	(.15)	(.19)

Quarterly and year-to-date computations of loss per share amounts are made independently. Therefore, the sum of the per share amounts for the quarters may not agree with the per share amounts for the year.

NOTE 19 SUBSEQUENT EVENT

On April 4, 2005, the Company completed a private placement of 4,100,000 shares of its Common Stock, at a price of $3.50 per share, resulting in net proceeds of $13.5 million. The proceeds will be used to fund the Company s working capital requirements over the next 12 months.

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INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM
REPORT ON SCHEDULE

To the Board of Directors
STAAR Surgical Company

The audits referred to in our report dated March 16, 2005, except for Note 19 which is as of April 4, 2005, relating to the consolidated financial statements of STAAR Surgical Company and Subsidiaries, which is contained in Item 8 of this Annual Report on Form 10-K included the audit of Schedule II, Valuation and Qualifying Accounts and Reserves as of December 31, 2004, and for each of the three years in the period ended December 31, 2004. This financial statement schedule is the responsibility of the Company s management. Our responsibility is to express an opinion on this financial statement schedule based on our audit.

In our opinion, such financial statement schedule presents fairly, in all material respects, the information set forth therein.

By: /s/ BDO Seidman, LLP

Los Angeles, California
March 16, 2005, except for Note 19 which is as of April 4, 2005.

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STAAR SURGICAL COMPANY AND SUBSIDIARIES
SCHEDULE II VALUATION AND QUALIFYING ACCOUNTS AND RESERVES

Column A	Column B	Column C	Column D	Column E
Description	**Balance at Beginning of Year**	**Additions**	**Deductions**	**Balance at End of Year**
		(In thousands)		
2004				
Allowance for doubtful accounts and sales returns deducted from accounts receivable in balance sheet	$ 734	$ 236	$ 510	$ 460
Deferred tax asset valuation allowance	22,075	6,097		28,172
Notes receivable reserve		500		500
	$ 22,809	$ 6,833	$ 510	$ 29,132
2003				
Allowance for doubtful accounts and sales returns deducted from accounts receivable in balance sheet	$ 805	$ 108	$ 179	$ 734
Deferred tax asset valuation allowance	18,607	3,468		22,075
Notes receivable reserve	1,795		1,795	
	$ 21,207	$ 3,576	$ 1,974	$ 22,809
2002				
Allowance for doubtful accounts and sales returns deducted from accounts receivable in balance sheet	$ 768	$ 1,186	$ 1,149	$ 805
Accrued restructuring costs	100		100	
Deferred tax asset valuation allowance	4,288	14,319		18,607
Notes receivable reserve	3,609		1,814	1,795
	$ 8,765	$ 15,505	$ 3,063	$ 21,207