



FORM 10-K

STAAR SURGICAL CO – STAA

Filed: March 15, 2006 (period: December 30, 2005)

Annual report which provides a comprehensive overview of the company for the past year

Table of Contents

PART I

Item 1. Business 2

PART I

Item 1. Business
Item 1A. Risk Factors
Item 1B. Unresolved Staff Comments
Item 2. Properties
Item 3. Legal Proceedings
Item 4. Submission of Matters to a Vote of Security Holders

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters, and Issuer Purchases of
Item 6. Selected Financial Data
Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations
Item 7A. Quantitative and Qualitative Disclosures About Market Risk
Item 8. Financial Statements and Supplementary Data
Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure
Item 9A. Controls and Procedures
Item 9B. Other Information

PART III

Item 10. Directors and Executive Officers of the Registrant
Item 11. Executive Compensation
Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters
Item 13. Certain Relationships and Related Transactions
Item 14. Principal Accountant Fees and Services

PART IV

Item 15. Exhibits and Financial Statement Schedules

SIGNATURES

EX-23.1 (Consents of experts and counsel)

EX-31.1

[EX-31.2](#)

[EX-32.1](#)

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

Form 10-K

(Mark One)

- ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 30, 2005
or
- 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
*(State or other jurisdiction of
incorporation or organization)*

95-3797439
*(I.R.S. Employer
Identification No.)*

1911 Walker Avenue
Monrovia, California
(Address of principal executive offices)

91016
(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 if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes No

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of "accelerated filer" or "large accelerated filer" in Rule 12b-2 of the Act.

Large accelerated filer Accelerated filer Non-accelerated filer

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes No

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant as of July 1, 2005, the last business day of the registrant's most recently completed second fiscal quarter, was approximately \$102,620,000 based on the closing price per share of \$5.15 of the registrant's Common Stock on that date.

The number of shares outstanding of the registrant's Common Stock as of March 8, 2006 was 24,918,541.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement relating to its 2006 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.



TABLE OF CONTENTS

		<u>Page</u>
	<u>PART I</u>	
Item 1.	Business	2
Item 1A.	Risk Factors	12
Item 1B.	Unresolved Staff Comments	22
Item 2.	Properties	22
Item 3.	Legal Proceedings	22
Item 4.	Submission of Matters to a Vote of Security Holders	23
	<u>PART II</u>	
Item 5.	Market for Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities	23
Item 6.	Selected Financial Data	24
Item 7.	Management’s Discussion and Analysis of Financial Condition and Results of Operations	25
Item 7A.	Quantitative and Qualitative Disclosures About Market Risk	38
Item 8.	Financial Statements and Supplementary Data	39
Item 9.	Changes in and Disagreements with Accountants on Accounting and Financial Disclosure	39
Item 9A.	Controls and Procedures	39
Item 9B.	Other Information	40
	<u>PART III</u>	
Item 10.	Directors and Executive Officers of the Registrant	40
Item 11.	Executive Compensation	40
Item 12.	Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	40
Item 13.	Certain Relationships and Related Transactions	40
Item 14.	Principal Accountant Fees and Services	40
	<u>PART IV</u>	
Item 15.	Exhibits and Financial Statement Schedules	41
Signatures		45
Exhibit 23.1		
Exhibit 31.1		
Exhibit 31.2		
Exhibit 32.1		

PART I

This Annual Report on Form 10–K contains statements that 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. Readers can recognize forward–looking statements by the use of words like “anticipate,” “estimate,” “expect,” “project,” “intend,” “plan,” “believe,” “will,” “target,” “forecast” and similar expressions in connection with any discussion of future operating or financial performance. STAAR Surgical Company cautions investors and prospective investors 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 1A. Risk Factors.”

Item 1. *Business*

General

STAAR Surgical Company develops and manufactures visual implants and other innovative ophthalmic products to improve or correct the vision of patients with cataracts and refractive conditions and distributes them worldwide. 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”), available in both three–piece and one–piece designs, 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:

- Silicone Toric IOLs, used in cataract surgery to treat astigmatism;
- Preloaded Injector, a three–piece silicone IOL preloaded into a single–use disposable injector;
- 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, a medical device system, used to remove a cataract patient’s cloudy lens, that has low energy and high vacuum characteristics; and
- Cruise Control, a disposable filter which allows for a faster, cleaner phacoemulsification procedure and is compatible with all phacoemulsification equipment utilizing Venturi and peristaltic pump technologies.

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.

Refractive Surgery. In the area of refractive surgery, we have used our biocompatible Collamer material to develop and manufacture implantable Collamer lenses (“ICLs”). STAAR’s VISIAN™ ICL and VISIAN™ Toric ICL (“TICL”) 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 IOL, which replaces a cataract patient’s cloudy lens, these products are designed to work with the patient’s natural lens to correct refractive disorders. The surgeon implants the foldable ICL or TICL through a tiny incision, generally under local anesthesia. STAAR began selling the ICL outside the U.S. in 1996 and the TICL in 2002. These products are sold in approximately 41 countries. The Company’s goal is to establish the ICL and TICL as the next paradigm shift in refractive surgery, making the products increasingly significant revenue generators for the Company beginning in 2006.

The U.S. Food and Drug Administration (the “FDA”) approved the ICL for use in treating myopia on December 22, 2005. While the U.S. roll–out of this product remains in its earliest stage, we believe that the ICL will be a viable choice for refractive surgery and could replace cataract surgery products as STAAR’s largest

source of revenue. The ICL and TICL are approved for use in countries that require the European Union CE Mark and in Korea, Singapore, and Canada. Applications are pending in China and Australia, and the Company is working to obtain new approvals for the ICL and TICL in other countries. The Company has completed enrollment in the U.S. clinical trials for the TICL and expects to file its submission with the FDA at the end of the first quarter or early in the second quarter of 2006.

Background

The human eye is a specialized sensory organ capable of receiving visual images and transmitting them to the visual center in the brain. The main parts of the eye are the cornea, the iris, the lens, the retina, and the 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 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 posterior chamber of the eye, located behind the iris and in front of the natural lens, is filled with a watery fluid called the aqueous humor, while the portion of the eye behind the lens is filled with a jelly-like material called the vitreous humor. 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 humor.

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 disorder that involves the hardening and loss of transparency of the natural crystalline lens, impairing visual acuity.

Refractive disorders, which are generally not age-related, include myopia, hyperopia, and astigmatism. A normal, well functioning eye receives images of objects at varying distances from the eye and focuses the images on the retina. Refractive errors occur when the eye's natural optical system does not properly focus an image on the retina. Myopia, also known as nearsightedness, occurs when the eye's lens focuses images in front of the retina. Hyperopia, or farsightedness, occurs when the eye's lens focuses images behind the plane of the retina. Individuals with myopia or hyperopia may also have astigmatism. Astigmatism is blurred vision caused when an irregularly shaped cornea or, in some cases, a defect in the natural lens, produces a distorted image on the retina. 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 its focus for varying distances.

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 began selling the ICL outside the U.S. Made of STAAR's proprietary biocompatible Collamer® lens material, the ICL is implanted behind the iris and in front of the patient's natural lens to treat refractive errors such as myopia, hyperopia and astigmatism. The ICL received CE Marking in 1997, permitting sales in countries that require the European Union CE Mark, and it received FDA approval for the treatment of myopia in the U.S. in December 2005. The ICL is now sold in approximately 41 countries and has been implanted in more than 50,000 eyes worldwide.

Other milestones in STAAR's history include the following:

- In 1998, STAAR introduced the Toric IOL, the first implantable lens approved for the treatment of astigmatism. Typically used in cataract surgery, the Toric IOL was STAAR's first venture into the refractive market in the United States.
- In 2000, STAAR introduced an IOL made of the Collamer material, making its clarity, refractive qualities, and biocompatibility available to cataract patients and their surgeons.

[Table of Contents](#)

- In 2001, STAAR commenced commercial sales of its VISIAN Toric ICL (“TICL”), which corrects both astigmatism and myopia, outside the U.S. In 2002 the TICL received CE Marking, allowing commercial sales in countries that require the European Union CE Mark. The TICL is not yet approved for commercial sale in the U.S.
- In late 2003, STAAR, through its Japanese 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.
- On December 22, 2005, the FDA approved the ICL for the treatment of myopia, making it the first small incision phakic implant commercially available in the United States.

Financial Information about Segments and Geographic Areas

STAAR’s principal products are IOLs and ancillary products used in cataract and refractive surgery. As such, 100% of STAAR’s sales are generated from the ophthalmic surgical product segment and, therefore, the Company operates as one operating segment for financial reporting purposes. See Note 17 to the Consolidated Financial Statements for financial information about product lines and operations in geographic areas

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. Because they can be folded, our IOLs 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.

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.

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

In late 2003, we introduced through our joint venture company, Canon Staar, the first preloaded lens injector system in international markets. The Preloaded Injector is a disposable lens delivery system containing a three-piece silicone IOL that is sterilized and ready for implant. We believe the Preloaded Injector offers surgeons improved convenience and reliability. The Preloaded Injector is not yet available in the U.S.

Sales of IOLs accounted for approximately 52% of our total revenues for the 2005 fiscal year, 56% of total revenues for the 2004 fiscal year and 61% of total revenues for the 2003 fiscal year.

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, a medical device system that uses ultrasound to remove a cataract patient’s cloudy lens through a small incision and has low energy and high vacuum characteristics, and Cruise Control, a single-use disposable filter which allows for a 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

[Table of Contents](#)

approximately 36% of our total revenues for the 2005 fiscal year, 32% of total revenues for the 2004 fiscal year and 29% of total revenues for the 2003 fiscal year.

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 refractive errors over a wide diopter range.

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 natural lens is not removed. The surgical procedure to implant the ICL is typically performed with topical anesthesia on an outpatient basis. Visual recovery is usually 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 for myopia was approved by the FDA for use in the United States on December 22, 2005. The ICL and TICL are approved in countries that require the European Union CE Mark, Canada, Korea and Singapore. Applications are pending in China and Australia, and the Company is working to obtain new approvals for the ICL and TICL in other countries. The Company has completed enrollment in the U.S. clinical trials for the TICL and expects to file its submission with the FDA in at the end of the first quarter or early in the second quarter of 2006.

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

The ICL is available for myopia in the United States in four lengths and 27 powers for each length, and internationally 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 500 inventoried parts. This requires the Company to carry a significant amount of inventory to meet the customer demand for 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. Accordingly, the Toric ICL is made to order.

Sales of ICLs (including TICLs) accounted for approximately 10% of our total revenues for the 2005 fiscal year, 8% of total revenues for the 2004 fiscal year and 6% of total revenues for the 2003 fiscal year.

Other Products

AquaFlow Collagen Glaucoma Drainage Device. Among STAAR’s other products is the AquaFlow Collagen Glaucoma Drainage Device, an implantable device used for the surgical treatment of glaucoma. 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.

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 STAAR has seen continuing interest by surgeons in learning the surgical procedure to implant the AquaFlow Device, the market for this product is not expanding due to several factors, including the conservative nature of the glaucoma market, the time needed to train ophthalmic surgeons to perform the surgical procedure and the need to develop instruments or new product designs to simplify the implantation procedure. Sales of AquaFlow Devices accounted for approximately 1% of our total revenues in 2005, and 2% of our total revenues in each of the 2004 and 2003 fiscal years.

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.

Our sources of supply for raw materials can be threatened by shortages of raw materials and other market forces, by natural disasters, by the supplier's failure to maintain adequate quality or a recall initiated by the supplier. Even when substitute suppliers are available, the need to certify regulatory compliance and quality standards of substitute suppliers could cause significant delays in production and a material reduction in our sales revenue. We try to mitigate this risk by stockpiling raw materials when practical and identifying secondary suppliers, but the risk cannot be entirely eliminated. For example, the failure of one of our suppliers could be the result of an unforeseen industry-wide problem, or the failure of our supplier could create an industry-wide shortage affecting secondary suppliers as well.

In particular, loss of our external supply source for silicone could cause us material harm. In addition, 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 30, 2005, we owned approximately 155 United States and foreign patents and had approximately 64 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 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.

[Table of Contents](#)

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 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 generally experience lower sales during the third quarter due to the effect of summer vacations on elective procedures. In particular, because sales activity in Europe drops dramatically in the summer months, and European sales have recently accounted for a greater proportion of our total sales, this seasonal variation in our results has become even more pronounced.

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. In the United States and Canada we primarily sell through a network of independent manufacturers' representatives. We compensate the independent representatives through sales commissions. They 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.

Competition

Competition in the ophthalmic surgical product market 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. Accordingly, we must 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 competitors in the development and sale of products used to surgically correct cataracts, specifically foldable IOLs and phacoemulsification machines, include Alcon Laboratories ("Alcon"), Advanced Medical Optics ("AMO"), and Bausch & Lomb. According to a 2005 Market Scope report, Alcon holds 50% of the U.S. IOL market, followed by AMO with 27% and Bausch & Lomb with 12%. We hold approximately 8% 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 55% 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 improved three-piece Collamer IOL and injector system will strengthen our position and help reverse the decline in our overall IOL market share. Although the market for Silicone IOLs, which currently account for 40% of the U.S. market, has declined in recent years, we believe they still provide an opportunity for us as we introduce improvements in silicone IOL technology and build market awareness of our Collamer IOLs and improved injection systems.

Our ICL faces significant competition in the marketplace from other products and procedures that improve or correct refractive conditions, such as corrective eyeglasses, external contact lenses, and conventional and laser refractive surgical procedures. These products and procedures are long established in the marketplace and familiar to patients in need of refractive correction. In particular, eyeglasses and external contact lenses are much cheaper and more easily obtained, because a prescription for the product 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 seeking surgery to correct refractive conditions: Advanced Medical Optics (AMO) Alcon, Bausch & Lomb, Nidek and Wave Light. All of these companies 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 +.75 to +3.0 diopters. In the phakic implant market, there are only two approved phakic IOLs available in the U.S., our VISIAN™ ICL and the AMO Verisyse. In international markets, our ICL's main competition is the Ophtec Artisan IOL, although there are several other phakic IOLs, manufactured by various companies, which are also available.

Regulatory Matters

Regulatory Requirements

We must secure and maintain regulatory approval to sell our products in the United States and in most foreign countries. We are also subject to various federal, state, local and foreign laws that apply 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 regulatory regimes that govern our manufacturing and sale of our products.

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 do the following:

- set standards for medical devices,
- require proof of safety and effectiveness prior to marketing devices that 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 the export of devices 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 that 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”) required before commercial marketing). Class III devices are the most extensively regulated because the FDA has determined they are life-supporting, 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, ICLs, and AquaFlow Devices are Class III devices, our 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, the ICL for the treatment of myopia, 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. The requirements for approval or clearance to market medical products in foreign countries vary widely. 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 others, 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 Conformance’ 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 (except for the Collamer three-piece IOL which we expect to receive in the second half of 2006), SonicWAVE Phacoemulsification System and our AquaFlow Device.

U.S. Approval of the ICL

The FDA Office of Device Evaluation approved the VISIAN ICL for the treatment of myopia on December 22, 2005. The approved models are indicated for the correction of myopia in adults with myopia ranging from –3.0 to less than or equal to –15.0 diopters with astigmatism less than or equal to 2.5 diopters at the spectacle plane, and the reduction of myopia in adults with myopia ranging from greater than –15.0 to –20.0 diopters with astigmatism less than or equal to 2.5 diopters at the spectacle plane, in patients 21 to 45 years of age with anterior chamber depth (ACD) 3.00 mm or greater, and a stable refractive history within 0.5 diopters for one year prior to implantation.

STAAR plans to submit a supplemental pre-market approval application for the TICL during the first quarter of 2006 or early in the second quarter. The Company is also conducting clinical trials on the hyperopic ICL for the U.S. market.

Recent Proceedings With the FDA Office of Compliance

After an inspection of STAAR's Monrovia, California facility in August and September of 2003, STAAR received Form 483 Inspectional Observations, Warning Letters, and other correspondence from the FDA's Office of Compliance indicating that the FDA deemed STAAR's Monrovia, California facility to be violating the FDA's Quality System Regulations and Medical Device Reporting regulations. In a Warning Letter received on December 29, 2003 the FDA warned of possible enforcement action and stated that it would not approve premarket applications for the approval of Class III devices (such as the ICL) until related violations of the Quality System Regulation were corrected. These violations were last asserted by the FDA in a letter received on July 5, 2005, which stated that the agency found STAAR's earlier responses inadequate.

STAAR responded to the FDA's observations and assertions by implementing numerous improvements to its quality system in consultation with the agency and independent consultants. Among other things, STAAR developed a Global Quality Systems Action Plan, which has been continuously updated since its adoption in April, 2004, and took steps to emphasize a focus on compliance throughout the organization.

In 2005, STAAR undertook a compliance initiative that included a comprehensive revision of its operating procedures to ensure alignment with all FDA regulations and the international ISO 13485 standard, training to implement the new procedures and the enhancement of its internal audit function to provide for self-regulation by verifying compliance and ensuring corrective action for noncompliance.

The FDA reinspected STAAR's Monrovia, California facility between August 29, 2005 and September 14, 2005. Based on the results of the reinspection, and the FDA's final approval of the VISIAN ICL on December 22, 2005, STAAR believes that it is now substantially in compliance with the FDA's Quality System Regulations and Medical Device Reporting regulations.

Nevertheless, the FDA's findings of compliance deficiencies during the preceding two years have harmed our reputation in the ophthalmic industry and affected our product sales, and delayed FDA approval of the ICL. STAAR's ability to continue its U.S. business depends on the continuous improvement of its quality systems and its ability to demonstrate substantial compliance with FDA regulations. Accordingly, for the foreseeable future STAAR's management expects its strategy to include devoting significant resources and attention to those efforts.

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 28 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 compliance and quality 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,
- improving manufacturing systems and procedures for all products to reduce manufacturing costs and improve yields, and
- developing products and extending foreign registrations.

[Table of Contents](#)

Research and development expenses were approximately \$5,573,000, \$6,246,000, and \$5,120,000 for our 2005, 2004 and 2003 fiscal years, respectively. STAAR expects to pay at least a similar amount for research and development in 2006.

STAAR's research and development staff devoted significant resources to improving STAAR's regulatory and compliance systems during 2004 and 2005. STAAR believes it has achieved substantial compliance with the FDA's quality regulations and that the tasks of continuously improving quality and maintaining regulatory compliance can be borne by STAAR's quality and regulatory staffs. Accordingly, in future periods STAAR expects its research and development staff to shift resources devoted to improving regulatory compliance and quality systems to product development.

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 expect compliance with these laws to materially affect 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. In addition, we cannot predict changes in environmental 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, which distributes both STAAR products and products from other ophthalmic manufacturers.

Canon Staar Joint Venture

In 1988, STAAR entered into a Joint Venture Agreement with Canon Inc. and Canon Sales Co., Inc., creating a company for the principal purpose of designing, manufacturing, and selling in Japan intraocular lenses and other ophthalmic products. The joint venture company, Canon Staar Co., Inc., markets its products worldwide through Canon, Canon Sales, their subsidiaries and/or STAAR or such other distributors as the Board of Directors of the joint venture may approve. The terms of any such distribution arrangements require the unanimous approval of the Board of Directors of the joint venture. Of the five members of the Board of Directors of the joint venture, STAAR and Canon Sales are each entitled to appoint two directors and Canon may appoint one. The president of the joint venture is to be appointed by STAAR. Several matters require the unanimous approval of the directors, including appointment of officers, acquiring or disposing of assets exceeding 20% of the joint venture's total book value, and borrowing money or granting a lien exceeding 20% of the joint venture's total book value. Upon the occurrence of a merger, a 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.

In 1988, STAAR also entered into a Technical Assistance and Licensing Agreement with the joint venture to further its purposes, granting to the joint venture a perpetual exclusive license to use STAAR technology to make and sell products in Japan, and a perpetual non-exclusive license to use STAAR technology to sell products in the rest of the world, subject to the requirements of the Joint Venture Agreement that all sales take place through a distribution agreement unanimously approved by the directors of the joint venture. STAAR also granted to the joint venture a right of first refusal on the distribution of STAAR's products in Japan.

[Table of Contents](#)

In 2001, the parties entered into a settlement agreement whereby (i) they reconfirmed the Joint Venture Agreement and the Technical Assistance and Licensing Agreement, (ii) they agreed that the Company would promptly commence the transfer of STAAR's 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 STAAR's existing licenses and the existing rights of third parties), (iv) the Company agreed to provide the joint venture with raw materials under a supply agreement to be entered into with the joint venture, (v) Canon Sales is to enter into a distribution agreement with the joint venture providing a minimum 50–70% share of sales revenue to the joint venture and having such other terms as unanimously approved by the directors of the joint venture, and (vi) the parties settled certain patent disputes.

The joint venture has a single class of capital stock, of which STAAR owns 50%. Accordingly, STAAR is entitled to 50% of any dividends or distributions by the joint venture and 50% of the proceeds of any liquidation.

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 "*Item 1A. 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 24, 2006, we employed approximately 267 persons.

Code of Ethics

The Company has adopted a Code of Ethics that applies to all Company directors, officers, and employees. The Code of Ethics is posted on the Company's website, www.staar.com — *Investor Relations: Corporate Governance*.

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 1A. Risk Factors

Our short and long–term success is subject to many factors that are beyond our control. Investors and prospective investors should consider carefully the following risk factors, in addition to other information contained in this report. This Annual Report on Form 10–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 \$71.7 million as of December 30, 2005. There can be no assurance that we will report net income in any future period.

We have only limited working capital.

We believe that our current sources of working capital are sufficient to satisfy our anticipated working capital requirements for fiscal 2006. However, the declining sales of our cataract products and the delay in U.S. approval for the ICL raise uncertainties about the sufficiency of our working capital for future years and we may have to consider alternative sources of funding. We can provide no assurance as to the availability of such funding or the terms upon which it might be available.

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

As of December 30, 2005, we have outstanding balances on the credit facility of a European subsidiary of approximately \$1.7 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, our ability to obtain adequate financing on satisfactory terms or at all is limited. Any such financing may involve substantial dilution to existing shareholders. In addition, we have only approximately 1.31 million authorized shares of common stock that are unissued and that have not been reserved for issuance on the exercise of outstanding stock options as of December 30, 2005. This relatively small number of available shares limits our ability to raise equity capital by selling common stock or securities convertible into common stock unless our stockholders approve an amendment to our Certificate of Incorporation to increase the number of authorized shares of common stock. Even if additional authorized shares become available, equity financing at recently prevailing prices could result in substantial dilution to existing stockholders. An inability to secure additional financing could limit our ability to expand our business. If we fail to achieve profitability and cannot secure adequate funding our ability to continue operations would be in jeopardy.

Recent FDA compliance issues have harmed our reputation, and we expect to devote significant resources to maintaining compliance in the future.

The Office of Compliance of the FDA's Center for Devices and Radiological Health regularly inspects STAAR's facilities to determine whether we are in compliance with the FDA Quality System Regulations relating to such things as manufacturing practices, validation, testing, quality control, product labeling and complaint handling, and in compliance with FDA Medical Device Reporting regulations.

Based on the results of an FDA inspection of STAAR's Monrovia, California facility between August 29, 2005 and September 14, 2005, and the FDA's final approval of the VISIAN ICL, STAAR believes that it is substantially in compliance with the FDA's Quality System Regulations and Medical Device Reporting regulations. However, between December 29, 2003 and July 5, 2005 the Company received Warning Letters, Form 483 Inspectional Observations and other correspondence from the FDA indicating that the FDA deemed STAAR's Monrovia, California facility to be violating the FDA's Quality System Regulations and Medical Device Reporting regulations, warning of possible enforcement action and suspending approval of Class III medical devices to which the violations related.

The FDA's findings of compliance deficiencies during the preceding two years have harmed our reputation in the ophthalmic industry and affected our product sales and delayed FDA approval of the ICL. STAAR's ability to continue its U.S. business depends on the continuous improvement of its quality systems and its compliance with FDA regulations. Accordingly, for the foreseeable future STAAR's management expects its strategy to include devoting significant resources and attention to those efforts. STAAR cannot ensure that these efforts will always be successful, and any failure to demonstrate substantial compliance with these regulations can result in enforcement actions that terminate, suspend or severely restrict our ability to continue manufacturing and selling medical devices.

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

The FDA approved the sale of the ICL for treatment of myopia on December 22, 2005. The ICL will not reach its full sales potential unless we successfully plan and execute its launch and marketing in the United States. This presents 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. Final training of surgeons in the U.S. will be conducted by a finite number of proctors on our staff. Our resources are limited and we cannot 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 remains our largest source of sales. 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 STAAR silicone 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 IOLs made of a biocompatible lens material, Collamer, and more recently a three-piece silicone IOL preloaded into a single-use disposable injector which is sold internationally. Despite the introduction of these products, our overall cataract business has continued to decline in recent periods.

We face stronger competition from multifocal and accommodating lenses because of a change in Medicare reimbursement rules.

The Centers for Medicare and Medicaid Services recently changed the reimbursement policy applicable to cataract surgery by permitting Medicare-covered cataract patients to receive higher-cost multifocal IOLs by paying only the additional cost of the lens and surgical procedure while still receiving reimbursement for the basic cost of cataract surgery and a monofocal IOL. This has made the more costly cataract lenses that claim to reduce or eliminate the need for spectacles for close-up vision more accessible financially for older patients with active lifestyles. STAAR does not sell a multifocal or accommodating lens design and cannot participate in this market. Moreover, surgeons receive significant additional fees when they implant multifocal or accommodating lenses, so these procedures have absorbed significant time and attention of surgeons in our U.S. target market. Beginning in the second half of 2005, surgeons, including most of STAAR's customers, who wished to offer a multifocal option to patients by use of Alcon's ReSTOR® lens, were required to implant an Alcon monofocal IOL in each of at least thirty patients as a pre-requisite to training in implanting the ReSTOR lens. This generally resulted in the surgeon implanting sixty of our competitor's lenses in order to use the same lens in each of the patients' eyes, which contributed to STAAR's significant decline in U.S. sales during the third and fourth quarter of 2005. Competition from multifocal lenses under the new Medicare reimbursement rules will probably continue to take business from STAAR's domestic cataract business, but the full impact of this trend cannot be estimated at this time.

Our sales are subject to significant seasonal variation.

We generally experience lower sales during the third quarter due to the effect of summer vacations on elective procedures. In particular, because sales activity in Europe drops dramatically in July and August, and European sales have recently accounted for a greater proportion of our total sales, this seasonal variation in our results has become even more pronounced.

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 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 are relying on them, in part, to help introduce the ICL. 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. We may also be subject to recalls initiated by manufacturers of products we distribute. In February 2006, our German subsidiary recalled all lots of a balanced salt solution it distributes due to a manufacturer's recall for possible endotoxin content. In 2005, we recalled one lot of Phaco tubing manufactured by a third party, due to incorrect labelling, and we recalled one lot of STAARVISC, also manufactured by a third party, due to a potential sterility breach of the packaging of the cannula that is packaged with the STAARVISC. 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. While the majority of the direct costs associated with the recalls have not been material, we believe recalls have harmed our reputation and adversely affected our product sales, although the impact cannot be quantified. 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 been subject to product liability claims in the past and continue to be so. As part of our risk management policy, we have obtained third-party product liability insurance coverage. In recent periods this insurance has become more expensive and difficult to procure. Product liability claims against us may exceed the coverage limits of our insurance policies or cause us to record a loss in excess of our deductible. A 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 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 approximately 50 countries. Sales from international operations make up a significant portion of our total sales. For the year ended December 30, 2005, sales from international operations were 64% of total sales. 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 sales 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 sales. Inflation in 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 sales.

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 sale and

profitability, or harm our customer relations by delaying product deliveries. Even when substitute suppliers are available, the need to certify regulatory compliance and quality standards of substitute suppliers could cause significant delays in production and a material reduction in our sales revenue. We try to mitigate this risk by stockpiling raw materials when practical and identifying secondary suppliers, but the risk cannot be entirely eliminated. For example, the failure of one of our suppliers could be the result of an unforeseen industry-wide problem, or the failure of our supplier could create an industry-wide shortage affecting secondary suppliers as well.

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 and local 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.

STAAR and its Chief Executive Officer are defendants in a class action lawsuit pending in the Central District of California. A consolidated amended complaint filed by the plaintiffs on April 29, 2005 generally alleges that the defendants violated Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and Rule 10b-5 under the Exchange Act by issuing false and misleading statements regarding the prospects for FDA approval of STAAR's VISIAN ICL, thereby artificially inflating the price of the STAAR's Common Stock. The plaintiffs generally seek to recover compensatory damages, including interest. The defendants filed a motion to dismiss the lawsuit, which the court denied in an Order filed September 19, 2005. While permitting the case to proceed, the Order effectively narrowed the proposed class to purchasers of the Company's securities between October 6, 2003 and January 5, 2004 by limiting the statements of STAAR that the plaintiffs may challenge.

On December 27, 2005, the parties filed a Joint Status Report and Notice of Settlement with the court, indicating that the parties had entered into a Memorandum of Understanding agreeing in principal to settle the litigation. The terms of the proposed settlement are described more fully under "*Part I — Item 3 — Legal Proceedings.*" The proposed settlement will not be effective until the parties have executed and filed a Stipulation of Settlement and the court has granted final approval of the Stipulation of Settlement. Until that time the class action lawsuit remains pending.

From time to time we are 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.

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, an irrevocable, exclusive license to make and sell products using our technology in Japan. We have also granted the joint venture an irrevocable, exclusive license to make products using our technology in China and to sell in China and Japan the products made in China. In addition, we have granted Canon Staar an irrevocable, non-exclusive license to sell products using our technology in the rest of the world. Subject to the unanimous 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 directly or through distributors.

If a party to the Canon Staar joint venture undergoes a merger, sale of substantially all of its assets or changes its management, any of the other joint venture partners has the right to acquire that party's interest in the joint venture at book value. The terms of the principal agreements governing the joint venture are described under the caption "Business — Canon Staar Joint Venture."

Changes in accounting standards could affect our financial results.

The accounting rules applicable to public companies like STAAR are subject to frequent revision. Future changes in accounting standards could require us to change the way we calculate income, expense or balance sheet data, resulting in significant changes in our reported results of operation or financial condition.

We are subject to international taxation laws that could affect our financial results.

STAAR conducts international operations through its subsidiaries. Tax laws affecting international operations are highly complex and subject to change. STAAR's payment of income tax in the different countries where it operates depends in part on internal settlement prices and administrative charges among STAAR and its subsidiaries. These arrangements require judgments by STAAR and are subject to risk that tax authorities will disagree with those judgments and impose additional taxes, penalties or interest on STAAR. STAAR engages in dialogue with tax authorities in some of the countries where it operates to mitigate this risk, but it cannot be entirely eliminated. In addition, transactions that STAAR has arranged in light of current tax rules could have unforeseeable negative consequences if tax rules change.

If we suffer loss to our facilities due to catastrophe, our operations could be seriously harmed.

We depend on the continuing operation of all of our manufacturing facilities in California and Switzerland, which have little redundancy or overlap among their activities. Our facilities are subject to catastrophic loss due to fire, flood, earthquake, terrorism or other natural or man-made disasters. In particular, our California facilities are in areas where earthquakes could cause catastrophic loss. If any of these facilities were to experience a catastrophic loss, it could disrupt our operations, delay production, shipments and revenue and result in large expenses to repair or replace the facility. Although we carry insurance for property damage and business interruption, we do not carry insurance or financial reserves for interruptions or potential losses arising from earthquakes or terrorism.

If we are unable to protect our information systems against data corruption, cyber-based attacks or network security breaches, our operations could be disrupted.

We are increasingly dependent on information technology networks and systems, including the Internet, to process, transmit and store electronic information. In particular, we depend on our information technology infrastructure for electronic communications among our locations around the world and between Company personnel and our subsidiaries, customers, and suppliers. Security breaches of this infrastructure can create system disruptions, shutdowns or unauthorized disclosure of confidential information. If we are unable to prevent such security breaches, our operations could be disrupted or we may suffer financial damage or loss because of lost or misappropriated information.

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 sales 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 10.9% of our sales on research and development during the year ended December 30, 2005, and we expect to spend approximately 10% in future periods. 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, Medicaid, or other governmental sponsored programs. These third-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 sales.

Moreover, our products may not be covered in the future by third-party payors, which would also reduce our sales.

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. An unfavorable outcome in an FDA inspection may result in the FDA ordering changes in our business practices or taking other enforcement action, which could be costly and severely harm our business.

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.

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 sales; 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. 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.

We also have a Stockholders' Rights Plan, or "Poison Pill," which could discourage a third party from making an offer to acquire us. However the Stockholders' Rights Plan will expire on April 20, 2006, and our Board of Directors has no intention to renew or replace it at this time.

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;
- stockholders cannot act by written consent;
- 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 additional 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 \$3.12 to \$9.37 during the year ended December 30, 2005. 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 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.

Item 1B. Unresolved Staff Comments

None.

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 2006.

Item 3. Legal Proceedings

In re STAAR Surgical Co. Securities Litigation, No. CV 04-8007. The Company and its Chief Executive Officer are defendants in a class action lawsuit pending in the Central District of California. A consolidated amended complaint filed by the plaintiffs on April 29, 2005 generally alleges 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 the prospects for FDA approval of STAAR's VISIAN ICL, thereby artificially inflating the price of the Company's Common Stock. The plaintiffs generally seek to recover compensatory damages, including interest.

The defendants filed a motion to dismiss, which the court denied in an order filed September 19, 2005 (the "Order"). While permitting the case to proceed, the Order effectively narrowed the proposed class to purchasers of STAAR's securities between October 6, 2003 and January 5, 2004 by limiting the statements of STAAR that the plaintiffs may challenge.

On December 27, 2005, a Joint Status Report and Notice of Settlement (the "Notice") was filed with the court, indicating that the parties had reached an agreement to settle all claims. In the Notice, the parties to the Class Action Lawsuit informed the Court that they have reached an agreement to resolve the litigation, without admission of liability, and have signed a Memorandum of Understanding. The effectiveness of the agreement among the parties is subject to the parties' negotiating and approving the terms of a Stipulation of Settlement, and to the Court's final approval, after notice to the Class, of the terms set forth in that Stipulation.

The Memorandum of Understanding provides, among other things, that in consideration of their agreement to settle STAAR will pay to the plaintiffs total consideration of \$3,700,000. STAAR's insurance carrier has represented that the proceeds of insurance will cover those payments and all other costs related to settlement of the Class Action Lawsuit, except for approximately \$100,000 in administrative costs payable by the Company (which was accrued as of December 30, 2005) as part of its retention under the terms of its insurance policy.

The Stipulation of Settlement remains under negotiation among the parties. The Class Action Lawsuit remains pending until the Stipulation of Settlement is executed and filed by the parties and finally approved by the court.

From time to time the Company is subject 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.

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 30, 2005.

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:

<u>Period</u>	<u>High</u>	<u>Low</u>
2006		
First Quarter (through March 8, 2006)	\$ 8.660	\$ 6.630
2005		
Fourth Quarter	\$ 9.370	\$ 4.870
Third Quarter	6.050	3.120
Second Quarter	5.170	3.580
First Quarter	7.300	3.500
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

On March 8, 2006, the closing price of the Company's Common Stock was \$8.57. Stockholders are urged to obtain current market quotations for the Common Stock.

As of March 8, 2006, there were approximately 590 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 8, 2006, options to purchase 2,823,895 shares of Common Stock were exercisable.

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 30, 2005, December 31, 2004, January 2, 2004, January 3, 2003, and December 28, 2001. The selected consolidated statement of operations 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 30, 2005 and December 31, 2004, are derived from the consolidated financial statements which have been audited by BDO Seidman, LLP, independent registered public accounting firm, as indicated in their report which is included in this Annual Report. The selected consolidated statement of operations data set forth below for each of the two fiscal years in the periods ended January 3, 2003, and December 28, 2001, and the consolidated balance sheet data set forth below at January 2, 2004, January 3, 2003, and December 28, 2001 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 in this Annual Report, and "Management's Discussion and Analysis of Financial Condition and Results of Operations" in Item 7.

	Fiscal Year Ended				
	<u>December 30, 2005</u>	<u>December 31, 2004</u>	<u>January 2, 2004</u>	<u>January 3, 2003</u>	<u>December 28, 2001</u>
	(In thousands except per share data)				
Statement of Operations					
Sales	\$ 51,303	\$ 51,685	\$ 50,409	\$ 47,880	\$ 50,237
Royalty and other income	—	—	49	368	549
Total revenues	51,303	51,685	50,458	48,248	50,786
Cost of sales	27,517	25,542	22,621	24,099	28,203
Gross profit	23,786	26,143	27,837	24,149	22,583
Selling, general and administrative expenses					
General and administrative	9,727	9,253	9,343	8,959	8,746
Marketing and selling	18,552	20,302	19,509	16,833	20,043
Research and development	5,573	6,246	5,120	4,016	3,800
Other charges	746	500	390	1,454	7,780
Total selling, general and administrative expenses	34,598	36,301	34,362	31,262	40,369
Operating loss	(10,812)	(10,158)	(6,525)	(7,113)	(17,786)
Total other income (expense), net	854	(88)	(637)	(785)	(724)
Loss before income taxes and minority interest	(9,958)	(10,246)	(7,162)	(7,898)	(18,510)
Income tax provision (benefit)	1,239	1,057	1,127	8,805	(3,649)
Minority interest	(22)	29	68	75	139
Net loss	\$ (11,175)	\$ (11,332)	\$ (8,357)	\$ (16,778)	\$ (15,000)
Basic and diluted net loss per share	\$ (0.47)	\$ (0.58)	\$ (0.47)	\$ (0.98)	\$ (0.88)
Weighted average number of basic and diluted shares	23,704	19,602	17,704	17,142	17,003
Balance Sheet Data					
Working capital	\$ 22,735	\$ 19,103	\$ 15,883	\$ 7,095	\$ 16,780
Total assets	52,755	51,973	47,376	45,220	64,650
Notes payable and current portion of long-term debt	1,676	3,004	2,950	5,845	8,216
Stockholders' equity	40,366	37,840	35,219	30,551	46,142

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

The matters addressed in Management's Discussion and Analysis of Financial Condition and Results of Operations that are not historical information 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. Readers can recognize forward-looking statements by the use of words like "anticipate," "estimate," "expect," "project," "intend," "plan," "believe," "will," "target", "forecast" and similar expressions in connection with any discussion of future operating or financial performance. In particular, these include statements relating to future actions, prospective products or product approvals, future performance or results of current and anticipated products, sales efforts, expenses, interest rates, foreign exchange rates, the outcome of contingencies, such as legal proceedings, and financial results.

Although the Company believes that the expectations reflected in these forward-looking statements are reasonable, such statements are inherently subject to risks and the Company can give no assurance that its expectations will prove to be correct. Actual results could differ from those described in this report because of numerous factors, many of which are beyond the control of the Company. These factors include, without limitation, those described in this Annual Report in "Item 1 — Risk Factors." The Company undertakes no obligation to update these forward-looking statements after the date of this report to reflect future events or circumstances or to reflect actual outcomes.

The following discussion should be read in conjunction with the audited consolidated financial statements of STAAR, including the related notes, provided in this report.

Overview

Strategy

STAAR is currently focusing on the following four strategic goals:

- successfully launching the ICL in the U.S. market and securing U.S. approval of the TICL;
- generating further growth of the ICL and TICL in international markets;
- reversing the decline in U.S. market share for our core cataract product lines by renewing and refining our product offering through enhanced R&D; and
- maintaining our focus on regulatory compliance and continuous quality improvement.

Successfully launching the ICL in the U.S. market and securing U.S. approval of the TICL. STAAR's VISIAN ICL is the first implantable lens to be sold for the correction of myopia in the U.S. that is foldable, and therefore minimally invasive. U.S. Surgeons who had developed expertise in implanting the ICL during our clinical trials began implanting the ICL in new patients on January 10, 2006, and STAAR began its pre-launch in a rollout to qualify ICL surgeons on January 27, 2006. STAAR makes the ICL available to selected surgeons only after completion of a training program that includes proctoring of selected supervised surgeries. STAAR believes that this carefully guided method of product release is essential to help ensure the consistent quality of patient outcomes and the high levels of patient satisfaction needed to establish wide acceptance of the ICL as a choice for refractive surgery. In international markets, this approach has resulted in relatively slow but steady and sustained growth in sales over the last few years. STAAR believes that the TICL, a variant of the ICL that corrects both astigmatism and myopia in a single lens, also has a significant potential market in the U.S. Securing FDA approval of the TICL is therefore an integral part of STAAR's strategy to develop its U.S. refractive market. Because the application for FDA approval of the TICL is considered a supplement to the pre-market application for the ICL, it could not be submitted until after approval of the ICL was granted. STAAR has completed clinical trials for the TICL and intends to submit its application for U.S. approval of the TICL around the end of the first quarter or early in the second quarter of 2006.

Generating further growth of the ICL and TICL in international markets. In markets where the ICL and TICL have been approved, STAAR has gradually increased its share of the refractive implant market and of the overall market for refractive surgery. STAAR has principally emphasized the superior visual outcomes the ICL

can provide in patients who fall outside the ideal range for LASIK surgery and similar procedures. STAAR believes that when surgeons using the ICL for those patients become accustomed to the predictable, superior outcomes of the ICL, they may begin offering it to a broader range of patients as an alternative to cornea-based procedures. STAAR bases this belief on the fact that in most markets, over time, the sales of mid-powered ICLs increases as a proportion of total sales. When surgeons and patients choose the ICL for lower levels of correction, the size of its potential market increases greatly.

In addition, the introduction of the TICL in international markets has strengthened our refractive offering and contributed to accelerated sales growth for both the ICL and TICL. Because it is designed to provide a customized solution for a wide array of refractive errors, the TICL is made in numerous powers and must be custom ordered. The time required to fill orders has been a challenge to STAAR in marketing the TICL. STAAR has recently been able to commit to more rapidly delivery of the TICL, which has allowed us to win market share from other phakic implants. STAAR believes that for a large number of patients with both myopia and astigmatism the TICL can provide an outcome that is superior to that of any other surgical procedure. When measured six months after surgery, approximately 75% of the patients receiving the TICL have shown better visual acuity than the best they previously achieved with glasses or contact lenses.

STAAR continues to seek new approvals for the ICL and TICL in other countries. During the second quarter of 2005, STAAR received market approvals for the TICL in Canada and Korea and for both the ICL and TICL in Singapore. STAAR believes it could obtain approval for the ICL and TICL in China around the end of the first quarter or early in the second quarter of 2006.

Reversing the decline in U.S. market share for our core cataract product lines by intensifying selling efforts and renewing and refining our product offering through enhanced R&D. STAAR pioneered the foldable IOL for use in cataract surgery. Sales of IOLs and other cataract-related products still make up 88% of STAAR's total revenue. However, over the last several years STAAR has experienced declining U.S. sales of IOLs. STAAR seeks to reverse the decline in its domestic cataract market share by intensifying its selling efforts in the improved environment resulting from ICL approval. In addition, the resolution of FDA compliance issues has enabled STAAR to shift R&D resources to developing improved cataract products intended to help reverse the decline.

STAAR's management believes that the erosion STAAR's U.S. cataract market share principally resulted from our sales representatives' lack of effective selling time with our target surgeon market. In recent periods, our independent sales representatives have had difficulty obtaining selling time with receptive surgeons because of two factors: lack of improved or innovative products to introduce, and negative publicity resulting from FDA compliance issues and past concerns about STAAR's financial stability. A more detailed discussion of these problems is provided under the caption "*Recent Highlights — Decline in U.S. Sales of IOL*" below.

Management believes that approval of the ICL in the U.S. and the resolution of STAAR's issues with the FDA Office of Compliance have improved the sales environment for STAAR's cataract products as well. STAAR has developed a combined sales incentive plan for its independent representatives, which is intended to capitalize on the interest in the ICL among ophthalmologists by encouraging intensified selling efforts in our cataract product line along with the sales of the ICL.

Accomplishing U.S. ICL approval and resolving FDA compliance issues has also enabled STAAR to shift its R&D resources to the initiative to renew and revamp its cataract product offering. The first product offering from this effort is a redesigned three-piece Collamer IOL and a newly designed delivery system, which we introduced to the U.S. market in 2005. While the outcome of R&D is never certain, STAAR's management believes that its investments in cataract technology in fiscal 2006 may yield further improved and enhanced products that will generate greater sales interest.

To reverse the decline in U.S. IOL sales, STAAR must overcome several short and long-term challenges. In particular, overcoming reputational harm will take time. We cannot ensure that this strategy will ultimately be successful.

Maintaining our focus on regulatory compliance and continuous quality improvement. As a manufacturer of medical devices, STAAR's manufacturing processes and facilities are subject to regulation by the FDA. Failure to demonstrate compliance with FDA regulations can result in enforcement actions that terminate, suspend

or severely restrict the ability to continue manufacturing and selling medical devices. Between December 29, 2003 and July 5, 2005 STAAR received Warning Letters, Form 483 Inspectional Observations and other correspondence from the FDA indicating deficiencies in STAAR's compliance with the FDA's Quality System Regulations and Medical Device Reporting regulations and warning of possible enforcement action. In response, STAAR implemented numerous improvements to its quality system. Among other things, STAAR developed a Global Quality Systems Action Plan, which has been continuously updated since its adoption in April, 2004, and took steps to emphasize a focus on compliance throughout the organization.

Based on the results of the FDA's most recent inspection of STAAR's Monrovia, California facility between August 29, 2005 and September 14, 2005 and the FDA's final approval of the VISIAN ICL, STAAR believes that it is substantially in compliance with the FDA's Quality System Regulations and Medical Device Reporting regulations. Nevertheless, the FDA's findings of compliance deficiencies have harmed our reputation in the ophthalmic industry and affected our product sales, and likely resulted in a significant delay in FDA approval of the ICL. STAAR's ability to continue its U.S. business depends on the continuous improvement of its quality systems and its ability to demonstrate compliance with FDA regulations. Accordingly, for the foreseeable future STAAR's management expects its strategy to include devoting significant resources and attention to strict regulatory compliance and continuous improvement in quality.

Financing Strategy

While STAAR's international business generates positive cash flow and 64% of STAAR's revenue, STAAR has reported losses on a consolidated basis for each of the last three fiscal years due to a number of factors, including eroding sales of cataract products in the U.S. and FDA compliance issues that consumed additional resources while delaying the introduction of new products in the U.S. market. During the last three years STAAR has secured additional capital to sustain operations through private sales of equity securities.

STAAR's management believes that in the near term its best prospect for returning its U.S. and consolidated operations to profitability is the successful launch of the ICL in the U.S. In the longer term STAAR seeks to develop and introduce products in the U.S. cataract market to stop further erosion of its market share and resume growth in that sector. Nevertheless, success of these strategies is not assured and, even if successful, STAAR is not likely to achieve positive cash flow on a consolidated basis during fiscal 2006.

To avoid, if possible, additional rounds of equity financing and potential dilution to the interests of existing stockholders, STAAR plans to finance its operations, including the U.S. launch of the ICL, through funds from operations and existing cash resources. STAAR is also seeking a line of credit through a U.S. bank, and its Swiss subsidiary has \$824,000 in borrowing availability under its \$2.5 million line of credit for use in Swiss operations. STAAR's cash resources are discussed in further detail under the caption "*Liquidity and Capital Resources*" below.

To maximize the effective use of its cash resources, STAAR implemented a number of cost reduction strategies beginning in the fourth quarter of 2004. For the full year 2005, the Company used approximately \$6,976,000 for operating activities, which is 21% below the Company's cash usage of \$8,804,000 for 2004.

The success of STAAR's financing strategy is not assured and is subject to numerous contingencies and risks, including those discussed under "*Item 1A. Risk Factors.*" STAAR may find it necessary to raise additional capital in the future through the sale of equity securities, but STAAR has only 1.31 million shares of common stock authorized for issuance as of December 30, 2005, that have not already been issued or reserved for issuance on the exercise of outstanding options. To address this issue, STAAR's board of directors adopted a resolution to submit a proposal to the stockholders at the Annual Meeting to increase STAAR's authorized shares of common stock. STAAR has limited access to financing, and if its funds from operations, cash and access to borrowing are not sufficient to support operations STAAR may not be able to secure financing on favorable terms or at all.

Recent Highlights

Decline in U.S. Sales of IOLs. Several factors led to a 14% decline in total U.S. sales during 2005, from \$21.6 million to \$18.7 million. STAAR's management believes that, above all, the decline has resulted from our sales representatives' lack of effective selling time with our target surgeon market. Our independent

Table of Contents

sales representatives have had difficulty obtaining selling time with receptive surgeons because of two factors: negative publicity resulting from FDA compliance issues and past concerns about STAAR's financial stability, and a lack of improved or innovative products to introduce.

In a number of documents, including Form 483 observations, warning letters, and in particular a letter received from the FDA on July 5, 2005, the FDA found STAAR to be in violation of provisions of the FDA's Quality System Regulation and Medical Device Reporting regulations and indicated that regulatory action against STAAR was possible. STAAR believes the issues raised by the FDA were resolved by the fourth quarter of 2005, and believes it is substantially in compliance with FDA regulations. Nevertheless, negative publicity surrounding the FDA proceedings damaged STAAR's quality reputation with customers and led to doubts about STAAR's ability to continue its domestic business.

In addition, in their original report on the Company's audited financial statements for fiscal year 2004, the Company's independent registered public accounting firm included a qualifying paragraph expressing substantial doubt about the Company's ability to continue as a going concern. While this qualification was withdrawn following the Company's receipt of the proceeds of a private placement of common stock on April 4, 2005, doubt about the Company's ability to continue to support its products caused some customers to curtail purchases of our products.

The uncertainty created by the above factors worsened a sales environment that was already difficult because of STAAR's failure in recent years to match the pace of its competitors in improving IOL technology and standard lens delivery systems. The slow pace of improvements, in turn, resulted from STAAR's need to invest in developing and commercializing its ICL technology and in revamping its quality systems, which left limited resources for developing new and enhanced lenses and injector systems for cataract treatment. STAAR has introduced some innovative products during this period, including IOLs made of the same uniquely biocompatible Collamer material used in the ICL and the first preloaded injector system, which was developed by STAAR's joint venture company in Japan, Canon Staar. However, the preloaded injector is not yet approved for sale in the U.S. and these products did not significantly increase surgeons' receptiveness to our representatives' selling efforts.

The poor sales environment has severely hampered our representatives' ability to gain selling time to generate new business and preserve our existing domestic business. As discussed above under the caption "*Strategy — Reversing the decline in U.S. market share for our core cataract product lines by intensifying selling efforts and renewing and refining our product offering through enhanced R&D,*" STAAR believes that the U.S. launch of the ICL and the recent resolution of compliance issues with the FDA have provided an opportunity to gain selling time for our representatives in a more favorable sales environment.

STAAR introduced the redesigned three-piece Collamer IOL and newly designed delivery system to the U.S. market in 2005. Sales of this lens have been encouraging, comprising approximately 8% of STAAR's total U.S. IOL sales in the fourth quarter of 2005.

Sales in the third and fourth quarters were also affected by a ruling of the Centers for Medicare and Medicaid Services ("CMS"). The ruling permits Medicare-covered cataract patients to receive higher-cost multifocal IOLs by paying only the additional cost of the lens and surgical procedure while still receiving reimbursement for the basic cost of cataract surgery and a monofocal IOL. Surgeons who wished to offer this alternative to patients, including most of STAAR's customers, by use of Alcon's ReSTOR® lens, were required to implant an Alcon monofocal IOL in at least thirty patients as a pre-requisite to training in implanting the ReSTOR lens. This generally resulted in the surgeon implanting sixty of our competitor's lenses in order to use the same lens in each of the patients' eyes, and as a consequence, STAAR likely lost significant sales. While STAAR expects some rebound in sales, the CMS ruling and the ability of surgeons to offer multifocal lenses with partial Medicare reimbursement is expected to continue to affect sales of STAAR's IOLs in future periods.

Growth in International Sales of VISIAN ICLs and Preloaded Silicone IOLs. The decline in the U.S. cataract business during 2005 was offset in part by a 30% increase in international sales of the VISIAN ICL and TICL. In addition, the preloaded silicone IOL injector system developed with our joint venture partner Canon

[Table of Contents](#)

Staar experienced strong sales in international markets, growing 85% for the year. This growth in the business contributed to an increase in international sales of 9% for fiscal 2005 compared with 2004.

Seasonality. We generally experience lower sales during the third quarter due to the effect of summer vacations on elective procedures. In particular, because sales activity in Europe drops dramatically in the summer months, and European sales have recently accounted for a greater proportion of our total sales, this seasonal variation in our results has become even more pronounced.

Foreign Currency Fluctuations. Our products are sold in approximately 50 countries. During fiscal year 2005, sales from international operations represented 64% of total sales. 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 fiscal year 2005, changes in currency exchange rates did not have a material impact on net sales and marketing and selling expenses.

Gross Profit. Our gross profit margin decreased to 46.4% for fiscal year 2005, compared with 50.6% in 2004. The decline in gross profit from 2004 generally resulted from higher unit costs as a result of manufacturing process changes and reduced volume, and a shift in geographical and product mix. The Company expects the U.S. launch of the ICL, with its higher margins, to improve gross profit.

Research and Development. We spent approximately 11% of our sales on research and development (which includes regulatory and quality assurance expenses) during fiscal 2005, and we expect to spend approximately 10% of our sales on an annual basis in the future.

Private Placements. Due to 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 \$13.4 million and 2,000,000 shares of our Common Stock on June 10, 2004, which generated net proceeds of \$11.6 million.

Cash Flow. The Company used approximately \$7.0 million for operating activities during fiscal 2005, which is 21% below the Company's cash usage of \$8.8 million during fiscal 2004. During the fourth quarter of 2004, we took steps to reduce operating expenses by reducing our reliance on outside consultants. This reduction in spending resulted in savings of approximately \$1.3 million. In early February 2005, we implemented additional cost reduction strategies, including the reduction in size of our direct sales force, which resulted in another \$825,000 in annualized cost savings. Use of cash for the fourth quarter of 2005 was 41% below that in the fourth quarter of 2004. We will continue to pursue other cost savings opportunities, wherever possible, to conserve cash. The Company expects to reverse its operating losses and negative cash flows as ICL sales reach targeted levels for 2007.

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. The Company and its Chief Executive Officer are defendants in a class action lawsuit pending in the Central District of California on behalf of all persons who purchased the Company's securities during various periods of 2003 and 2004. On December 27, 2005, a Joint Status Report and Notice of Settlement was filed with the Central District of California, indicating that the parties to the lawsuit had reached an agreement in principal to settle on all claims. A Stipulation of Settlement is currently being negotiated by the parties. Until the parties agree to the Stipulation Settlement and it is finally approved by the court the case will remain pending. Please see the discussion under "Part I. Item 3. Legal Proceedings."

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 30, 2005	December 31, 2004	January 2, 2004	2005 vs. 2004	2004 vs. 2003
Total revenues	100.0%	100.0%	100.0%	(0.7)%	2.4%
Cost of sales	53.6%	49.4%	44.8%	7.7%	12.9%
Gross profit	46.4%	50.6%	55.2%	(9.0)%	(6.1)%
Costs and expenses:					
General and administrative	19.0%	17.9%	18.5%	5.1%	(1.0)%
Marketing and selling	36.2%	39.3%	38.7%	(8.6)%	4.1%
Research and development	10.9%	12.1%	10.1%	(10.8)%	22.0%
Other charges	1.4%	1.0%	0.8%	49.3%	28.2%
Total costs and expenses	67.5%	70.3%	68.1%	(4.7)%	5.6%
Operating loss	(21.1)%	(19.7)%	(12.9)%	6.4%	55.7%
Other expense, net	1.7%	(0.1)%	(1.3)%	—	(86.2)%
Loss before income taxes	(19.4)%	(19.8)%	(14.2)%	(2.8)%	43.1%
Income tax provision (benefit)	2.4%	2.0%	2.2%	17.4%	(6.2)%
Minority interest	0.0%	0.1%	0.1%	—	(57.4)%
Net loss	(21.8)%	(21.9)%	(16.5)%	(1.4)%	35.6%

2005 Fiscal Year Compared to 2004 Fiscal Year

Revenues. Net sales for the years ended December 30, 2005 (“fiscal 2005”) and December 31, 2004 (“fiscal 2004”) were \$51.3 million and \$51.7 million, respectively. Changes in currency exchange rates did not have a material impact on net sales for fiscal 2005. The primary reason for the decrease in product sales was a decrease in U.S. cataract product sales, both in average selling prices and volumes, due to (i) increasing concerns in the marketplace regarding the Company's long unresolved compliance issues with the FDA, (ii) the Company's failure to match competitors' improvements to IOL technology, (iii) although subsequently withdrawn, the receipt of a going concern qualification from the Company's auditors; (iv) our sales representatives' loss of effective selling time as a result of the foregoing; (v) a supplier recall of viscoelastic which is often bundled with IOLs; and (vi) the CMS ruling that permits Medicare-covered cataract patients to receive higher-cost multifocal IOLs by paying only the additional cost of the lens and surgical procedure while still receiving reimbursement for the basic cost of cataract surgery and a monofocal IOL. The decreases in U.S. cataract product sales were partially offset by a 30% increase in sales of the Company's VISIAN™ ICL (“ICL”) and VISIAN™ Toric ICL (“TICL”) in international markets, and an 85% increase in sales of preloaded IOLs in international markets.

Gross profit. Gross profit margin decreased to 46.4% of revenues for fiscal 2005, from 50.6% of revenues for fiscal 2004. The primary reasons for the decrease in gross profit margin were higher unit costs due to the allocation of fixed overhead across fewer units produced, lower overall average selling prices of IOLs, and a continued shift in geographical and product mix. The Company expects gross profit margin to improve gradually with the launch of the ICL in the United States.

General and administrative expenses. General and administrative expenses for fiscal 2005 increased \$474,000, or 5%, over fiscal 2004 primarily due to increased insurance premiums and increased professional fees, particularly legal and settlement fees associated with the class action lawsuit. The Company does not expect significant increases in general and administrative expenses in 2006.

Marketing and selling expenses. Marketing and selling expenses for fiscal 2005 decreased \$1.8 million, or 8.6%, over fiscal 2004 primarily as a result of cost reduction measures taken during 2005 and a decrease in

U.S. commissions due to decreased cataract product sales. The Company expects marketing and selling expenses to increase approximately \$2,500,000 in 2006 as a result of increased promotional activities associated with the launch of the ICL in the U.S. Further, marketing and selling expenses in the U.S. will also increase as a result of increased commissions associated with the ICL.

Research and development expenses. Research and development expenses for the fiscal 2005, decreased \$673,000, or 10.8%, compared to fiscal 2004, as anticipated, because significant consulting costs were incurred in the previous year in preparation for FDA audits in the Company's Nidau, Switzerland and Monrovia, California facilities. The Company expects research and development expenses to increase in 2006 based upon planned IOL development activities, costs associated with the TICL supplement to be filed with the FDA, and the initiation of ICL post-marketing studies.

Other charges. Other charges for fiscal 2005 were \$746,000 compared to \$500,000 in fiscal 2004. During fiscal 2005, the Company recorded additional reserves totaling \$746,000 against promissory notes of a former director of the Company. Aggregate principal and accrued interest owed to the Company under the notes was \$1.9 million as of December 30, 2005, against which the Company has reserved a total of \$1.2 million. The former Director is in default under the notes and a related Forbearance Agreement with the Company, but has recently affirmed his obligation to pay the full principal and interest under the notes.

On these events, the Company re-evaluated its likelihood of collecting on the notes and re-examined the collateral for the notes, which consists of a pledge of 120,000 shares of the Company's Common Stock (the "Pledged Shares") and a second mortgage on a home in Florida. During the third quarter of 2005, the Company was advised that its collateral may be compromised with respect to the second mortgage. Accordingly, the Company increased its reserve on the notes to reflect the status of the collateral.

Notwithstanding the additional reserve amount, the Company believes the former director is obligated to repay the full amount of principal and interest on the notes, and continues to pursue full repayment of the notes.

Other income (expense), net. Other income, net for fiscal 2005 was \$854,000, compared to fiscal 2004 when it was expense of \$88,000. The principal reasons for the increase in other income are due to 1) \$334,000 of exchange gains recorded during the year versus \$190,000 of exchange losses recorded during fiscal 2004; 2) increased interest income due to higher cash balances and interest rates; and 3) \$158,000 in earnings from the Company's joint venture versus \$191,000 of losses recorded during fiscal 2004.

Income taxes. The Company recorded income taxes of \$1.2 million for fiscal 2005 and \$1.1 million for fiscal 2004, primarily based on the income of the Company's German subsidiary.

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 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

[Table of Contents](#)

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 hired 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 fiscal 2004, increased \$1,126,000, 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, at the time, totaled \$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 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.

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 directors’ notes, and the exercise of stock options.

As of December 30, 2005 and December 31, 2004, the Company had \$12.7 million and \$9.3 million, respectively, of cash, cash equivalents and short–term investments.

Net cash used in operating activities was \$7.0 million, \$8.8 million, and \$4.1 million for fiscal 2005, 2004, and 2003, respectively. For fiscal 2005, cash used in operations was the result of the net loss, adjusted for depreciation, amortization, notes receivable reserves and other non–cash charges, and net increases in working capital. For fiscal 2004, cash used in operations was the result of the net loss, adjusted for depreciation, amortization, notes receivable reserves and other non–cash charges, and net decreases in working capital. 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.

Accounts receivable was \$5.1 million in 2005, \$6.2 million in 2004, and \$5.7 million in 2003. The decrease in accounts receivable is due to decreased sales in the U.S. during fiscal 2005 and in Germany, in the fourth quarter of 2005 and the effect of changes in exchange rates. Days Sales Outstanding (“DSO”) increased slightly from 39 days in 2003 to 41 days in 2004, and decreased to 38 days in 2005. The Company expects DSO to improve further in 2006 with the launch of the ICL in the U.S. which have shorter payment terms than cataract product.

Inventory at year-end 2005, 2004, and 2003 was \$14.7 million, \$15.1 million, and \$12.8 million, respectively. Day's inventory on hand decreased from 204 days in 2003 to 186 days in 2004, and increased to 235 days in 2005. The increase in days inventory on hand from 2004 to 2005 is due to decreased sales in the U.S. without a corresponding decrease in inventories. Despite decreased sales, the Company increased its minimum inventory levels to resolve backorder issues it faced during the year. In terms of the dollar change, inventory at the end of 2005 decreased \$385,000 compared to 2004 primarily due to the impact of changes in currency exchange rates, in particular the Euro. Although inventory units 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.

Net cash provided by (used in) investing activities was approximately \$4,077,000, (\$7,294,000), and \$2,151,000 for fiscal 2005, 2004, and 2003, respectively. During 2005, the Company invested \$13.4 million of the proceeds of a private placement and additional \$1.9 million in cash in taxable auction-rate securities which were classified as available for sale investments and sold \$7.8 million of the investment during the year to provide cash for operations. During the third quarter of 2005, the Company sold all of its remaining auction-rate securities totaling \$12.6 million and purchased high-quality commercial paper, which is classified as a cash equivalent. 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. The principal investments of the Company are in property and equipment. Investments in property and equipment were \$1.2 million, \$1.7 million, and \$1.3 million for fiscal 2005, 2004, and 2003, respectively. The investments are generally made to upgrade and improve existing production equipment and processes. The Company expects to spend approximately \$1.4 million on property and equipment in 2006.

Net cash provided by financing activities was approximately \$12,298,000, \$12,547,000, and \$7,589,000 for fiscal 2005, 2004, and 2003, respectively. In 2005, cash provided by financing activities resulted from the receipt of net proceeds of \$13.4 million from a private placement of 4.1 million shares of the Company's Common Stock and \$130,000 received from the exercise of the stock options. During 2005, the Company used \$1.2 million in cash generated from international operations to pay down (while retaining availability) the Company's Swiss credit facility. 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 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. During 2003, 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.

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 3.25 million Swiss Francs "CHF" (approximately \$2.5 million based on the exchange rate on December 30, 2005), and permits either fixed-term or current advances. The interest rate on current advances was 6.0% per annum at December 30, 2005 and 6.0% per annum at December 31, 2004, plus a commission rate of 0.25% payable quarterly. There were no current advances outstanding at December 30, 2005 or December 31, 2004. The base interest rate for fixed-term advances follows Euromarket conditions for loans of a corresponding term and currency, plus an individual margin (4.25% at December 30, 2005 and 4.5% at December 31, 2004). Borrowings outstanding under the facility were CHF 2.2 million at December 30, 2005 (approximately \$1.7 million based on the exchange rate on December 30, 2005) and CHF 3.4 million at December 31, 2004 (approximately \$3.0 million based on the exchange rate on December 31, 2004). The credit facility is secured by a general assignment of claims and includes positive and negative covenants which, among other things, require the

[Table of Contents](#)

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 (\$2.3 million based on the exchange rate on December 30, 2005) and does not have a termination date. Part B presently provides for borrowings of up to CHF 250,000 (\$190,000 based on the exchange rate on December 30, 2005). The loan amount under Part B of the agreement is reduced by CHF 250,000 (\$190,000 based on the exchange rate on December 31, 2004) semi-annually. As of December 30, 2005, approximately \$824,000 was available under the credit facility for future borrowings for use in Swiss operations.

The German subsidiary renewed its credit agreement on August 30, 2005. The renewed credit agreement provides for borrowings of up to 100,000 EUR (\$119,000 based on the exchange rate on December 30, 2005), at a rate of 7.0% per annum and does not have a termination date. The credit facility is not secured. There were no borrowings outstanding as of December 30, 2005 and December 31, 2004.

The Company was in compliance with the covenants of these credit facilities as of December 30, 2005.

The following table represents the Company's known contractual obligations as of December 30, 2005 (in thousands):

<u>Contractual Obligations</u>	<u>Payments Due by Period</u>				
	<u>Total</u>	<u>Less Than 1 Year</u>	<u>1-3 Years</u>	<u>3-5 Years</u>	<u>More Than 5 Years</u>
Notes payable and other current liabilities	\$ 1,776	\$ 1,776	\$ —	\$ —	\$ —
Capital lease obligations	177	51	126	—	—
Operating lease obligations	3,030	1,179	1,485	366	—
Purchase obligations	2,094	600	1,494	—	—
Open purchase orders	363	363	—	—	—
Other long-term liabilities	868	—	868	—	—
Total	<u>\$ 8,308</u>	<u>\$ 3,969</u>	<u>\$ 3,973</u>	<u>\$ 366</u>	<u>\$ —</u>

The table presented above excludes employment agreements for the two previous minority owners of our Australian subsidiary. See Note 9 to the Consolidated Financial Statements.

While the Company's international business generates positive cash flow and represents 64% of consolidated net sales, the Company has reported losses on a consolidated basis for each of the last three fiscal years due to a number of factors, including eroding sales of cataract products in the U.S. and FDA compliance issues that consumed additional resources while delaying the introduction of new products in the U.S. market. During the last three years the Company has secured additional capital to sustain operations through private sales of equity securities. The Company believes that as a result of these financings, along with expected cash from operations, it currently has sufficient cash to meet its funding requirements over the next year.

The Company believes that in the near term its best prospect for returning its U.S. and consolidated operations to profitability is the successful launch of the ICL in the U.S. In the longer term the Company seeks to develop and introduce products in the U.S. cataract market to stop further erosion of its market share and resume growth in that sector. Nevertheless, success of these strategies is not assured and, even if successful, the company is not likely to achieve positive cash flow on a consolidated basis during fiscal 2006.

To avoid, if possible, additional rounds of equity financing and potential dilution to the interests of existing stockholders, the Company plans to finance its operations, including the U.S. launch of the ICL, through funds from operations and existing cash resources. The Company is also seeking a line of credit through a U.S. bank to provide an additional source of working capital for its U.S. operations, and its Swiss subsidiary has \$824,000 in borrowing capacity available for Swiss operations under its line of credit. However, given its history of losses and

[Table of Contents](#)

negative cash flows, there can be no assurance that the Company will be able to secure debt financing for its U.S. operations on favorable terms, if at all.

If it is unable to obtain additional debt financing, the Company may find it necessary to raise additional capital in the future through the sale of equity securities, but has only 1.31 million shares of common stock authorized for issuance as of December 30, 2005, that have not already been issued or reserved for issuance on the exercise of outstanding options. To address this issue, The Company's board of directors adopted a resolution to submit a proposal to the stockholders at the Annual Meeting to increase the Company's authorized shares of common stock.

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, which will be largely dependent on the success of the ICL, proceeds from the private placement of Common Stock, proceeds from option exercises, debt repayments by former directors, 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 also 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. Changes in the market price of our Common Stock affects the value of our outstanding options, and lower market prices could reduce our expected revenue from option exercises.

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 "*Item 1A. — 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 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 sales 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 on historical experiences, market trends and financial forecasts and projections, and on various other assumptions that management believes are reasonable under the circumstances and at that certain point in time. Actual results may differ, significantly at times, from these if actual conditions differ from our assumptions.

The Company believes the following represent its critical accounting policies.

- *Revenue Recognition and Accounts Receivable.* The Company recognizes revenue when it is realized or realizable and earned, based on terms of sale with the customer, generally upon product shipment. 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 sales from IOLs distributed on a consignment basis, which are recognized when we are notified that the lens has been implanted in a patient. During the normal course of business, the Company may offer terms, including extended credit terms, and arrangements that vary by product category, owing to the differing nature of the customers. The Company believes its revenue recognition policies are appropriate in all circumstances. See Note 1 *Accounting Policies* for a further discussion of the Company's revenue recognition policy.

The Company generally permits returns of product if the product is returned within the time allowed by the Company, and in good condition. The Company provides allowances for returns based on an analysis of our historical patterns of returns matched against the sales from which they originated. While such allowances have historically been within the Company's expectations, the Company cannot guarantee that

it will continue to experience the same return rates that it has in the past. Measurement of such returns requires consideration of historical return experience, including the need to adjust for current conditions and product lines, and judgments about the probable effects of relevant observable data. The Company considers all available information in its quarterly assessments of the adequacy of the allowance for returns.

The Company maintains provisions for uncollectible accounts based on estimated losses resulting from the inability of its customers to remit payments. If the financial condition of customers were to deteriorate, thereby resulting in an inability to make payments, additional allowances could be required. The Company performs ongoing credit evaluations of its customers and adjusts credit limits based upon customer payment history and current creditworthiness, as determined by the Company's review of its customers' current credit information. 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. While such credit losses have historically been within the Company's expectations and the provisions established, the Company cannot guarantee that it will continue to experience the same credit loss rates that it has in the past. Measurement of such losses requires consideration of historical loss experience, including the need to adjust for current conditions, and judgments about the probable effects of relevant observable data, including present economic conditions such as delinquency rates and financial health of specific customers. The Company considers all available information in its quarterly assessments of the adequacy of the reserves for uncollectible accounts.

- *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. We also disclose on a proforma basis the effect on our earnings if we used the fair-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 on 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 December 30, 2005, the valuation allowance fully offsets the value of deferred tax assets on the Company's balance sheet. Net increases to the valuation allowance were \$5,490,000, \$6,097,000 and \$3,468,000 in 2005, 2004 and 2003, respectively.

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.

In the normal course of business, the Company is regularly audited by federal, state and foreign tax authorities, and is periodically challenged regarding the amount of taxes due. These challenges include questions regarding the timing and amount of deductions and the allocation of income among various tax jurisdictions. Management believes the Company's tax positions comply with applicable tax law and

intends to defend its positions. The Company's effective tax rate in a given financial statement period could be impacted if the Company prevailed in matters for which reserves have been established, or was required to pay amounts in excess of established reserves.

- *Inventories.* The Company provides estimated inventory allowances for excess, slow moving and obsolete inventory as well as inventory whose carrying value is in excess of net realizable value. These reserves are based on current assessments about future demands, market conditions and related management initiatives. If market conditions and actual demands are less favorable than those projected by management, additional inventory write-downs may be required. The Company values its inventory at the lower of cost or net realizable market values. The Company regularly reviews inventory quantities on hand and records a provision for excess and obsolete inventory based primarily on the expiration of products with a shelf life of less than four months, estimated forecasts of product demand and production requirements for the next twelve months. Several factors may influence the realizability of its inventories, including decisions to exit a product line, technological change and new product development. These factors could result in an increase in the amount of obsolete inventory quantities on hand. Additionally, estimates of future product demand may prove to be inaccurate, in which case the provision required for excess and obsolete inventory may be understated or overstated. If in the future, the Company determined that its inventory was overvalued, it would be required to recognize such costs in cost of sales at the time of such determination. Likewise, if the Company determined that its inventory was undervalued, cost of sales in previous periods could have been overstated and the Company would be required to recognize such additional operating income at the time of sale. While such inventory losses have historically been within the Company's expectations and the provisions established, the Company cannot guarantee that it will continue to experience the same loss rates that it has in the past. Therefore, although the Company makes every effort to ensure the accuracy of forecasts of future product demand, including the impact of planned future product launches, any significant unanticipated changes in demand or technological developments could have a significant impact on the value of its inventory and its reported operating results. The Company recorded \$1,081,000, \$1,089,000 and \$845,000 in provisions to the Statements of Income for excess, slow moving and obsolete inventory in 2005, 2004 and 2003, respectively. At this time, management does not believe that anticipated product launches would have a material effect on the recovery of the Company's existing net inventory balances.
- *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. Certain factors which may occur and indicate that an impairment exists include, but are not limited to the following: significant underperformance relative to expected historical or projected future operating results; significant changes in the manner of the Company's use of the underlying assets; and significant adverse industry or market economic trends. 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. In the event that the carrying value of assets is determined to be unrecoverable, the Company would estimate the fair value of the assets and record an impairment charge for the excess of the carrying value over the fair value. The estimate of fair value requires management to make a number of assumptions and projections, which could include, but would not be limited to, future revenues, earnings and the probability of certain outcomes and scenarios. The Company's policy is consistent with current accounting guidance as prescribed by SFAS No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets*. An assessment was completed under the guidance of SFAS No. 144 during the fourth quarter of 2005, and no impairment was identified. See Note 1 *Accounting Policies* for a further discussion of SFAS No. 144.
- *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. Certain factors which may occur and indicate that an impairment exists include, but are not limited to the following: significant underperformance relative to expected historical or projected future operating results; significant changes in the manner of the Company's use of the underlying assets; and significant adverse industry or market economic trends. In the event that the carrying value of assets is determined to be unrecoverable, the Company would estimate the fair value of the reporting unit and record an impairment charge for the excess of the carrying value over the fair value. The estimate of fair value requires management to make a number of assumptions and projections, which could include, but would not be limited to, future revenues, earnings and the probability of certain outcomes and scenarios. The Company's policy is consistent with current accounting guidance as prescribed by SFAS No. 142, Goodwill and Intangible Assets. As provided under SFAS No. 142, an annual assessment was completed during the fourth quarter of 2005, and no impairment was identified. As of December 30, 2005, the carrying value of goodwill was \$7.5 million. See Note 1 *Accounting Policies* for a further discussion of SFAS No. 142.

- *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 \$6.6 million as of December 30, 2005. 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.

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. The Company does not engage in hedging transactions to offset changes in currency.

Inflation

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

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 \$1.7 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 \$17,000.

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 30, 2005, 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 1A. — 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 Annual Report on 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 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. Page F-3 of this Annual Report on Form 10-K sets forth the report of BDO Seidman, LLP, our independent registered public accounting firm, regarding its audit of STAAR’s internal control over financial reporting and 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, LLP report for a more complete understanding of the topics presented.

Evaluation of Disclosure Controls and Procedures

The Company’s management, with the participation of the CEO and CFO, conducted an evaluation of the effectiveness of the Company’s disclosure controls and procedures, as defined in Exchange Act Rule 13a-15(e), as of the end of the period covered by this Form 10-K. Based on that evaluation, the CEO and the CFO concluded that, as of the end of the period covered by this Form 10-K, the Company’s disclosure controls and procedures are effective in accumulating and communicating to them in a timely manner material information relating to the Company (including its consolidated subsidiaries) required to be included in its periodic reports filed with the Securities Exchange Commission.

Management Report on Internal Control Over Financial Reporting

The Company’s management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Exchange Act Rule 13a-15(f) and for assessing the effectiveness of its internal control over financial reporting. Our internal control system is designed to provide reasonable assurance to our management and Board of Directors regarding the preparation and fair presentation of published financial statements in accordance with United States’ generally accepted accounting principles.

The Company’s management, with the participation of the CEO and CFO, conducted an evaluation of the effectiveness of the Company’s internal control over financial reporting as of December 30, 2005, 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 30, 2005.

Because of its inherent limitations, a system of internal control over financial reporting can provide only reasonable assurance and may not prevent or detect misstatements. In addition, projections of any evaluation of effectiveness to future periods are subject to the risks that controls may become inadequate because of changes in conditions and that the degree of compliance with policies or procedures may deteriorate.

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 appears on Page F-3 of this Annual Report on Form 10-K.

Changes in Internal Control over Financial Reporting

There was no change during the fiscal quarter ended December 30, 2005, 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.

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 2006 annual meeting of stockholders to be filed with the Securities and Exchange Commission within 120 days of the close of the fiscal year ended December 30, 2005.

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

	<u>Page</u>
(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 30, 2005 and at December 31, 2004	F-4
Consolidated Statements of Operations for the years ended December 30, 2005, December 31, 2004, and January 2, 2004	F-5
Consolidated Statements of Changes in Stockholders' Equity and Comprehensive Loss for the years ended December 30, 2005, December 31, 2004, and January 2, 2004	F-6
Consolidated Statements of Cash Flows for the years ended December 30, 2005, December 31, 2004, and January 2, 2004	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-30
II. Schedule II — Valuation and Qualifying Accounts and Reserves	F-31

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 to date(7)
3.2	By-laws, as amended to date(8)
†4.1	1991 Stock Option Plan of STAAR Surgical Company(1)
†4.2	1995 STAAR Surgical Company Consultant Stock Plan(2)
†4.3	1996 STAAR Surgical Company Non-Qualified Stock Plan(3)
4.4	Stockholders' Rights Plan, dated effective April 20, 1995(8)
†4.5	1998 STAAR Surgical Company Stock Plan, adopted April 17, 1998(4)
4.6	Form of Certificate for Common Stock, par value \$0.01 per share(13)
†4.7	2003 Omnibus Equity Incentive Plan and form of Option Grant and Stock Option Agreement(12)
4.8	Amendment No. 1 to Stockholders' Rights Plan, dated April 21, 2003(14)
4.9	Registration Rights Agreement, dated June 4, 2004(18)
4.10	Registration Rights Agreement, dated March 31, 2005(21)
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.(6)
10.2	Settlement Agreement among the Company, Canon, Inc., Canon Sales Co., Inc., and Canon Staar Company, Inc. dated September 28, 2001(9)
10.3	Indenture of Lease dated September 1, 1993, between the Company and FKT Associates and First through Third Additions Thereto(8)
10.4	Second Amendment to Indenture of Lease dated September 21, 1998, between the Company and FKT Associates(8)
10.5	Third Amendment to Indenture of Lease dated October 13, 2003, by and between the Company and FKT Associates(16)

Table of Contents

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(5)
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(16)
10.9	Amendment No. 1 to Standard Industrial/ Commercial Multi-Tenant Lease dated January 3, 2003, by and between the Company and California Rosen(16)
10.10	Lease Agreement dated July 12, 1994, between STAAR Surgical AG and Calderari and Schwab AG/ SA(20)
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(20)
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(20)
10.13	Commercial Lease Agreement dated November 29, 2000, between Domilens GmbH and DePfa Deutsche Pfandbriefbank AG(20)
10.14	Patent License Agreement, dated May 24, 1995, with Eye Microsurgery Intersectoral Research and Technology Complex(15)
10.15	Patent License Agreement, dated January 1, 1996, with Eye Microsurgery Intersectoral Research and Technology Complex(8)
†10.16	Promissory Note dated June 16, 1999, from Peter J. Utrata to the Company(7)
†10.17	Stock Pledge Agreement dated June 16, 1999, by Peter J. Utrata in favor of the Company(7)
†10.18	Promissory Note dated June 2, 2000, from Peter J. Utrata to the Company(8)
†10.19	Stock Pledge Agreement dated June 2, 2000, between the Company and Peter J. Utrata(8)
†10.20	Mortgage dated July 16, 2004, between the Company and Peter J. Utrata(20)
†10.21	Forbearance Agreement dated July 22, 2004, between the Company and Peter J. Utrata(20)
†10.22	Employment Agreement dated December 19, 2000, between the Company and David Bailey(8)
†10.23	Stock Option Plan and Agreement for Chief Executive Officer dated November 13, 2001, between the Company and David Bailey(9)
†10.24	Stock Option Certificate dated August 9, 2001, between the Company and David Bailey(20)
†10.25	Stock Option Certificate dated January 2, 2002, between the Company and David Bailey(20)
†10.26	Stock Option Certificate dated February 14, 2003, between the Company and David Bailey(20)
†10.27	Amended and Restated Stock Option Certificate dated February 12, 2003, between the Company and David Bailey(20)
†10.28	Stock Option Certificate dated May 9, 2000, between the Company and Volker Anhaeusser(20)
†10.29	Stock Option Certificate dated May 31 2000, between the Company and Volker Anhaeusser(20)
†10.30	Stock Option Certificate dated May 30, 2002, between the Company and Volker Anhaeusser(20)
†10.31	Stock Option Agreement dated November 13, 2001, between the Company and David R. Morrison(9)
†10.32	Stock Option Certificate dated February 13, 2003, between the Company and Donald Duffy(20)
†10.33	Employment Agreement dated January 3, 2002, between the Company and John Bily(10)
†10.34	Stock Option Certificate dated January 18, 2002, between the Company and John C. Bily(20)
†10.35	Amended and Restated Stock Option Certificate dated February 12, 2003, between the Company and John C. Bily(20)
†10.36	Offer of Employment dated July 12, 2002, from the Company to Nick Curtis(20)
†10.37	Amendment to Offer of Employment dated February 14, 2003 from the Company to Nick Curtis(20)
†10.38	Stock Option Certificate dated February 14, 2003, between the Company and Nicholas Curtis(20)
†10.39	Amended and Restated Stock Option Certificate dated February 12, 2003, between the Company and Nicholas Curtis(20)
†10.40	Employment Agreement dated March 18, 2005, between the Company and Tom Paul(20)
†10.42	Form of Indemnification Agreement between the Company and certain officers and directors(20)

Table of Contents

†10.43	Managing Director’s Contract of Employment, dated June 22, 1993, between Domilens and Guenther Roepstorff(20)
†10.44	Supplementary Agreement #1 to the Managing Director’s Contract of Employment, dated November 25, 1997, between STAAR Surgical AG and Guenther Roepstorff(20)
†10.45	Supplementary Agreement #2 to the Managing Director’s Contract of Employment dated January 1, 1998, between Domilens and Guenther Roepstorff(20)
†10.46	Supplementary Agreement #3 to the Managing Director’s Contract of Employment dated January 1, 2003, between Domilens and Guenther Roepstorff(20)
†10.47	Employment Agreement dated May 5, 2004, between the ConceptVision Australia Pty Limited CAN 006 391 928 and Philip Butler Stoney(17)
†10.48	Employment Agreement dated May 5, 2004, between the ConceptVision Australia Pty Limited CAN 006 391 928 and Robert William Mitchell(17)
#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(11)
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(17)
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(17)
10.53	Stock Purchase Agreement dated June 4, 2004(18)
10.54	Master Credit Agreement dated August 2, 2004, between STAAR Surgical AG and UBS AG(19)
†10.56	Promissory Note dated March 29, 2002, between the Company and Pollet & Richardson(20)
†#10.57	Security Agreement dated March 29, 2002, between the Company and Pollet & Richardson(11)
10.58	Loan Agreement between Deutsche Postbank AG and Domilens GmbH dated August 30, 2005(22)
10.59	Standard Industrial/ Commercial Multi Tenant Lease — Gross dated October 6, 2005, entered into between the Company and Z & M LLC(22)
10.60	Stock Purchase Agreement dated March 31, 2005(21)
14.1	Code of Ethics(20)
21.1	List of Significant Subsidiaries(20)
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.

- (1) Incorporated by reference from the Company’s Registration Statement on Form S–8, File No. 033–76404, as filed on March 11, 1994.
- (2) Incorporated by reference from the Company’s Registration Statement on Form S–8, File No. 033–60241, as filed on June 15, 1995.
- (3) 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.

Table of Contents

- (4) 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.
- (5) 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.
- (6) 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.
- (7) 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.
- (8) 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.
- (9) 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.

- (10) Incorporated by reference to the Company's Quarterly Report, for the period ended June 28, 2002, as filed on August 12, 2002.
- (11) 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.
- (12) 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.
- (13) 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.
- (14) Incorporated by reference to the Company's Quarterly Report, for the period ended April 4, 2003, as filed on May 19, 2003.
- (15) 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.
- (16) 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.
- (17) Incorporated by reference to the Company's Quarterly Report, for the period ended April 2, 2004, as filed on May 12, 2004.
- (18) Incorporated by reference to the Company's Current Report on Form 8-K filed on June 9, 2004.
- (19) Incorporated by reference to the Company's Quarterly Report, for the period ended October 1, 2004, as filed on November 10, 2004.
- (20) 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.
- (21) Incorporated by reference to the Company's Current Report on Form 8-K filed on April 5, 2005.
- (22) Incorporated by reference to the Company's Quarterly Report for the period ended September 30, 2005, as filed on November 9, 2005.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this 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: March 15, 2006

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

<u>Name</u>	<u>Title</u>	<u>Date</u>
<u>/s/ David Bailey</u>	President, Chief Executive Officer and Director (principal executive officer)	March 15, 2006
David Bailey		
<u>/s/ Deborah Andrews</u>	Chief Financial Officer (principal accounting and financial officer)	March 15, 2006
Deborah Andrews		
<u>/s/ Don Bailey</u>	Chairman of the Board, Director	March 15, 2006
Don Bailey		
<u>/s/ Volker Anhaeusser</u>	Director	March 15, 2006
Volker Anhaeusser		
<u>/s/ Donald Duffy</u>	Director	March 15, 2006
Donald Duffy		
<u>/s/ David Morrison</u>	Director	March 15, 2006
David Morrison		
<u>/s/ David Schlotterbeck</u>	Director	March 15, 2006
David Schlotterbeck		

STAAR SURGICAL COMPANY AND SUBSIDIARIES
CONSOLIDATED FINANCIAL STATEMENTS
Years Ended December 30, 2005,
December 31, 2004 and January 2, 2004

TABLE OF CONTENTS

Report of Independent Registered Public Accounting Firm	F-2
Report of Independent Registered Public Accounting Firm	F-3
Consolidated Balance Sheets at December 30, 2005 and at December 31, 2004	F-4
Consolidated Statements of Operations for the years ended December 30, 2005, December 31, 2004, and January 2, 2004	F-5
Consolidated Statements of Changes in Stockholders' Equity and Comprehensive Loss for the years ended December 30, 2005, December 31, 2004, and January 2, 2004	F-6
Consolidated Statements of Cash Flows for the years ended December 30, 2005, December 31, 2004, and January 2, 2004	F-7
Notes to Consolidated Financial Statements	F-8

**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 30, 2005 and December 31, 2004, and the related consolidated statements of operations, changes in stockholders' equity, and cash flows for each of the three years in the period ended December 30, 2005. 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, 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 30, 2005 and December 31, 2004, and the consolidated results of their operations and their cash flows for each of the three years in the period ended December 30, 2005, 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 30, 2005, 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 15, 2006 expressed an unqualified opinion thereon.

/s/ BDO Seidman, LLP

Los Angeles, California
March 15, 2006

**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 30, 2005, 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 30, 2005, 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 30, 2005, 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 30, 2005 and December 31, 2004 and the related consolidated statements of operations, changes in stockholders' equity, and cash flows for each of the three years in the period ended December 30, 2005, and our report dated March 15, 2006 expressed an unqualified opinion thereon.

/s/ BDO Seidman, LLP

Los Angeles, California
March 15, 2006

STAAR SURGICAL COMPANY AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS
December 30, 2005 and December 31, 2004

	<u>2005</u>	<u>2004</u>
	(In thousands, except par value amounts)	
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 12,708	\$ 4,187
Short-term investments	—	5,125
Accounts receivable, less allowance for doubtful accounts and sales returns	5,100	6,217
Inventories	14,699	15,084
Prepays, deposits and other current assets	<u>1,763</u>	<u>1,969</u>
Total current assets	<u>34,270</u>	<u>32,582</u>
Investment in joint venture	283	125
Property, plant and equipment, net	5,595	6,163
Patents and licenses, net of accumulated amortization of \$6,569 and \$6,089	4,920	5,400
Goodwill	7,534	7,534
Other assets	<u>153</u>	<u>169</u>
Total assets	<u>\$ 52,755</u>	<u>\$ 51,973</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Notes payable	\$ 1,676	\$ 3,004
Accounts payable	4,014	5,313
Other current liabilities	<u>5,845</u>	<u>5,162</u>
Total current liabilities	11,535	13,479
Other long-term liabilities	<u>854</u>	<u>632</u>
Total liabilities	<u>12,389</u>	<u>14,111</u>
Minority interest	<u>—</u>	<u>22</u>
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$.01 par value, 10,000 shares authorized, none issued or outstanding	—	—
Common stock, \$.01 par value; 30,000 shares authorized; issued and outstanding 24,819 and 20,664 shares	248	207
Additional paid-in capital	112,434	98,691
Accumulated other comprehensive income	146	1,024
Accumulated deficit	<u>(71,653)</u>	<u>(60,478)</u>
Notes receivable from former directors	<u>(809)</u>	<u>(1,604)</u>
Total stockholders' equity	<u>40,366</u>	<u>37,840</u>
Total liabilities and stockholders' equity	<u>\$ 52,755</u>	<u>\$ 51,973</u>

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

STAAR SURGICAL COMPANY AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS
Years Ended December 30, 2005, December 31, 2004 and January 2, 2004

	<u>2005</u>	<u>2004</u>	<u>2003</u>
		(In thousands, except per share amounts)	
Sales	\$ 51,303	\$ 51,685	\$ 50,409
Royalty and other income	—	—	49
Total revenues	<u>51,303</u>	<u>51,685</u>	<u>50,458</u>
Cost of sales	<u>27,517</u>	<u>25,542</u>	<u>22,621</u>
Gross profit	<u>23,786</u>	<u>26,143</u>	<u>27,837</u>
Selling, general and administrative expenses:			
General and administrative	9,727	9,253	9,343
Marketing and selling	18,552	20,302	19,509
Research and development	5,573	6,246	5,120
Other charges	746	500	390
Total selling, general and administrative expenses	<u>34,598</u>	<u>36,301</u>	<u>34,362</u>
Operating loss	<u>(10,812)</u>	<u>(10,158)</u>	<u>(6,525)</u>
Other income (expense):			
Equity in earnings of joint venture	158	(191)	11
Interest income	453	219	256
Interest expense	(170)	(215)	(322)
Other income (expense), net	<u>413</u>	<u>99</u>	<u>(582)</u>
Total other income (expense), net	<u>854</u>	<u>(88)</u>	<u>(637)</u>
Loss before income taxes and minority interest	(9,958)	(10,246)	(7,162)
Provision for income taxes	1,239	1,057	1,127
Minority interest	<u>(22)</u>	<u>29</u>	<u>68</u>
Net loss	<u>\$ (11,175)</u>	<u>\$ (11,332)</u>	<u>\$ (8,357)</u>
Loss per share:			
Basic and diluted	<u>\$ (0.47)</u>	<u>\$ (0.58)</u>	<u>\$ (0.47)</u>
Weighted average shares outstanding			
Basic and diluted	<u>23,704</u>	<u>19,602</u>	<u>17,704</u>

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

STAAR SURGICAL COMPANY AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
AND COMPREHENSIVE LOSS
Years Ended December 30, 2005, December 31, 2004 and January 2, 2004

	Common Stock	Common Stock Par	Additional Paid-In	Accumulated Other Comprehensive	Accumulated	Notes	Total
	Shares	Value	Capital	Income (Loss)	Deficit	Receivable	
				(In thousands)			
Balance, at January 3, 2003	16,962	\$ 169	\$ 74,977	\$ (111)	\$ (40,789)	\$ (3,695)	\$ 30,551
Comprehensive loss:							
Net loss	—	—	—	—	(8,357)	—	(8,357)
Foreign currency translation adjustment	—	—	—	683	—	—	683
Total comprehensive loss							<u>\$ (7,674)</u>
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)
Balance, at January 2, 2004	18,403	184	85,948	572	(49,146)	(2,339)	35,219
Comprehensive loss:							
Net loss	—	—	—	—	(11,332)	—	(11,332)
Foreign currency translation adjustment	—	—	—	452	—	—	452
Total comprehensive loss							<u>\$ (10,880)</u>
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
Balance, at December 31, 2004	20,664	207	98,691	1,024	(60,478)	(1,604)	37,840
Comprehensive loss:							
Net loss	—	—	—	—	(11,175)	—	(11,175)
Foreign currency translation adjustment	—	—	—	(878)	—	—	(878)
Total comprehensive loss							<u>\$ (12,053)</u>
Common stock issued upon exercise of options	36	—	130	—	—	—	130
Common stock issued as payment for services	13	—	77	—	—	—	77
Stock-based consultant expense	—	—	203	—	—	—	203
Net proceeds from private placement	4,100	41	13,333	—	—	—	13,374
Restricted stock grants	6	—	37	—	—	—	37
Deferred compensation	—	—	(37)	—	—	—	(37)
Proceeds from notes receivable, net	—	—	—	—	—	130	130
Accrued interest on notes receivable	—	—	—	—	—	(81)	(81)
Notes receivable reserve	—	—	—	—	—	746	746
Balance, at December 30, 2005	<u>24,819</u>	<u>\$ 248</u>	<u>\$ 112,434</u>	<u>\$ 146</u>	<u>\$ (71,653)</u>	<u>\$ (809)</u>	<u>\$ 40,366</u>

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



STAAR SURGICAL COMPANY AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS
Years Ended December 30, 2005, December 31, 2004 and January 2, 2004

	<u>2005</u>	<u>2004</u>	<u>2003</u>
	(In thousands)		
Cash flows from operating activities:			
Net loss	\$ (11,175)	\$ (11,332)	\$ (8,357)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation of property and equipment	1,992	2,005	1,950
Amortization of intangibles	480	688	952
Write-off of patents	—	—	2,102
Loss on disposal of fixed assets	85	175	159
Equity in earnings of joint venture	(158)	191	(11)
Stock-based consultant expense	203	231	206
Common stock issued for services	77	60	279
Net change in notes receivable reserve	746	500	(1,796)
Other	(81)	(95)	308
Minority interest	(22)	21	104
Changes in working capital:			
Accounts receivable	1,117	(542)	474
Inventories	270	(2,282)	(1,041)
Prepays, deposits and other current assets	206	32	380
Accounts payable	(1,399)	769	351
Other current liabilities	683	775	(206)
Net cash used in operating activities	<u>(6,976)</u>	<u>(8,804)</u>	<u>(4,146)</u>
Cash flows from investing activities:			
Acquisition of property and equipment	(1,194)	(1,705)	(1,309)
Acquisition of patents and licenses	—	(16)	(75)
Purchase of short-term investments	(15,300)	(8,000)	—
Sale of short-term investments	20,425	2,875	—
Purchase of minority interest in subsidiary	—	(768)	—
Proceeds from notes receivable	130	330	3,270
Net change in other assets	16	(91)	189
Dividends received from joint venture	—	81	76
Net cash provided by (used in) investing activities	<u>4,077</u>	<u>(7,294)</u>	<u>2,151</u>
Cash flows from financing activities:			
Net borrowings (payments) under notes payable and long-term debt	(1,206)	72	(2,912)
Proceeds from the exercise of stock options and warrants	130	829	1,553
Net proceeds from private placement	13,374	11,646	8,948
Net cash provided by financing activities	<u>12,298</u>	<u>12,547</u>	<u>7,589</u>
Effect of exchange rate changes on cash and cash equivalents	(878)	452	683
Increase (decrease) in cash and cash equivalents	8,521	(3,099)	6,277
Cash and cash equivalents, at beginning of year	4,187	7,286	1,009
Cash and cash equivalents, at end of year	<u>\$ 12,708</u>	<u>\$ 4,187</u>	<u>\$ 7,286</u>

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

STAAR SURGICAL COMPANY AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
Years Ended December 30, 2005 and December 31, 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 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 significant 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.

Canon Staar Joint Venture

In 1988, the Company entered into a Joint Venture Agreement with Canon Inc. and Canon Sales Co., Inc., creating a company for the principal purpose of designing, manufacturing, and selling in Japan intraocular lenses and other ophthalmic products. The joint venture company, Canon Staar Co., Inc., markets its products worldwide through Canon, Canon Sales, their subsidiaries and/or STAAR or such other distributors as the Board of Directors of the joint venture may approve. The terms of any such distribution arrangements require the unanimous approval of the Board of Directors of the joint venture. Of the five members of the Board of Directors of the joint venture, STAAR and Canon Sales are each entitled to appoint two directors and Canon may appoint one. The president of the joint venture is to be appointed by STAAR. Several matters in addition to the approval of distribution arrangements require the unanimous approval of the directors, including appointment of officers, acquiring or disposing of assets exceeding 20% of the joint venture’s total book value, and borrowing money or granting a lien exceeding 20% of the joint venture’s total book value. 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.

In 1988, the Company also entered into a Technical Assistance and License Agreement with the joint venture to further its purposes, granting to the joint venture a perpetual, exclusive license to use STAAR technology to make and sell products in Japan, and a perpetual, non-exclusive license to use STAAR technology to sell products in the rest of the world, subject to the requirements of the Joint Venture Agreement that all sales take place through a distribution agreement unanimously approved by the directors of the joint venture. STAAR also granted to the joint venture a right of first refusal on the distribution of STAAR’s products in Japan.

In 2001, the parties entered into a settlement agreement whereby (i) they reconfirmed the Joint Venture Agreement and the Technical Assistance and License Agreement, (ii) they agreed that the Company would

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

promptly commence the transfer of STAAR's 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 STAAR's existing licenses and the existing rights of third parties), (iv) the Company agreed to provide the joint venture with raw materials under a supply agreement to be entered into with the joint venture, (v) Canon Sales Co., Inc. is to enter into a distribution agreement with the joint venture providing a minimum 50–70% share of sales revenue to the joint venture and having such other terms as unanimously approved by the directors of the joint venture, and (iv) the parties settled certain patent disputes.

The joint venture has a single class of capital stock, of which STAAR owns 50%. Accordingly, STAAR is entitled to 50% of any dividends or distributions by the joint venture and 50% of the proceeds of any liquidation.

Basis of Presentation

The accompanying consolidated financial statements include the accounts of the Company and its wholly owned and 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 period. Sales and expenses are translated at the weighted average of exchange rates in effect during the period. The resulting translation gains and losses are deferred and are shown as a separate component of stockholders' equity as accumulated other comprehensive income. During 2005, 2004 and 2003, the net foreign translation gain (loss) was (\$878,000), \$452,000 and \$683,000, respectively, and net foreign currency transaction gain (loss), included in the statement of operations in other income (expense), net, was \$334,000, (\$190,000) and (\$107,000), 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.

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.

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

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 and Cash Equivalents

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, if any, are included in income on the specific identification method.

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.

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.

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.

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

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 accounts for goodwill in accordance with Statement of Financial Accounting Standards (“SFAS”) No. 141, “Business Combinations,” and No. 142, “Goodwill and Other Intangible Assets.”

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 is tested for impairment on an annual basis or between annual tests if an event occurs or circumstances change that would indicate the carrying amount may be impaired. Impairment testing for goodwill is done at the reporting unit level. Reporting units are one level below the business segment level, but can be combined when reporting units within the same segment have similar economic characteristics. Under the criteria set forth by SFAS No. 142, the Company has determined that its reporting units have similar economic characteristics and therefore, can be combined into one reporting unit for the purposes of goodwill impairment testing. As provided under SFAS No. 142, an annual assessment was completed during fiscal year 2005 and no impairment was identified. As of December 30, 2005, 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 \$6.6 million as of December 30, 2005. 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 \$480,000, \$688,000 and \$952,000 for the years ended December 30, 2005, December 31, 2004 and January 2, 2004, respectively.

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

<u>Fiscal Year</u>	
2006	\$ 480
2007	480
2008	480
2009	480
2010	<u>380</u>
Total	<u>\$ 2,300</u>

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

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

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.

There were no impairments of long-lived assets identified during the years ended December 30, 2005 or December 31, 2004. 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 fiscal 2003. 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.

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 30, 2005, December 31, 2004, and January 2, 2004, 3.9 million, 3.1 million, and 3.2 million options to purchase shares of the Company's common stock, respectively, were excluded from the computation.

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.

The Company accounts for options granted to persons other than employees and directors under SFAS 123 and EITF 98-16, *Accounting for Equity Investments That Are Issued to Other Than Employees for Acquiring or in*

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

Conjunction with Selling Goods and Services. As such, the fair value of such options is periodically remeasured using the Black–Scholes option–pricing model and income or 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:

	<u>2005</u>	<u>2004</u>	<u>2003</u>
Dividend yield	0%	0%	0%
Expected volatility	70%	72%	69%
Risk–free interest rate	4.35%	4.22%	4.37%
Expected holding period (in years)	4.3	4.2	4.8

The weighted average fair value of options granted during the years ended December 30, 2005, December 31, 2004 and January 2, 2004 was \$2.55, \$4.11, and \$3.00, respectively.

Pro forma net loss and loss per share for fiscal years 2005, 2004, and 2003, 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):

	<u>2005</u>	<u>2004</u>	<u>2003</u>
Net loss			
As reported	\$ (11,175)	\$ (11,332)	\$ (8,357)
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	(1,038)	(739)	(1,563)
Pro forma net loss	<u>\$ (12,213)</u>	<u>\$ (12,071)</u>	<u>\$ (9,920)</u>
Basic and diluted loss per share			
As reported	\$ (0.47)	\$ (0.58)	\$ (0.47)
Pro forma	\$ (0.52)	\$ (0.62)	\$ (0.56)

In December 2004, the FASB issued SFAS No. 123 (revised) (“SFAS No. 123R”), “Share–Based Payment”. SFAS No. 123R eliminates the intrinsic value method under APB 25 as an alternative method of accounting for stock–based awards. SFAS No. 123R also revises the fair value–based method of accounting for share–based payment liabilities, forfeitures and modifications of stock–based awards and clarifies SFAS No. 123’s guidance in several areas, including measuring fair value, classifying an award as equity or as a liability and attributing compensation cost to reporting periods. In addition, SFAS No. 123R amends SFAS No. 95, “Statement of Cash Flows”, to require that excess tax benefits be reported as a financing cash inflow rather than as reduction of taxes paid, which is included in operating cash flows.

On April 14, 2005 the Securities and Exchange Commission announced a new rule delaying the implementation of Statement of Financial Accounting Standards No. 123R, Share–Based Payment. The Commission’s new rule allows companies to implement Statement No. 123R at the start of their next fiscal year, which begins after June 15, 2005. The Company is required to adopt SFAS No. 123R for the interim period beginning December 31, 2005 using a modified version of prospective application or may elect to apply a modified version of retrospective application. The Company currently expects to adopt SFAS No. 123R using the modified prospective method with an effective date of December 31, 2005, and believes the adoption of

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

SFAS No. 123R will result in increased losses in the Company's 2006 statement of operations, the extent of which is dependent on the number of options granted and other assumptions used in determining fair value.

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 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):

	<u>2005</u>	<u>2004</u>	<u>2003</u>
Net loss	\$ (11,175)	\$ (11,332)	\$ (8,357)
Foreign currency translation adjustment	(878)	452	683
Comprehensive loss	<u>\$ (12,053)</u>	<u>\$ (10,880)</u>	<u>\$ (7,674)</u>

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. Although the Company has expanded its marketing focus beyond the cataract market to include the refractive and glaucoma markets, the ophthalmic surgery market remains its primary source of revenues and, accordingly, the Company operates as one business segment (see Note 17).

Research and Development Costs

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

Note 2 — Short-Term Investments

Short-term investments consisted of the following at December 30, 2005 and December 31, 2004 (in thousands):

	<u>2005</u>		<u>2004</u>	
	<u>Cost</u>	<u>Market Value</u>	<u>Cost</u>	<u>Market Value</u>
Auction rate securities	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 5,125</u>	<u>\$ 5,125</u>
	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 5,125</u>	<u>\$ 5,125</u>

The short-term investments at December 31, 2004, 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 realized or unrealized gains or losses at December 31, 2004. The Company sold its auction rate securities during 2005.

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

Note 3 — Accounts Receivable

Accounts receivable consisted of the following at December 30, 2005 and December 31, 2004 (in thousands):

	<u>2005</u>	<u>2004</u>
Domestic	\$ 2,066	\$ 2,602
Foreign	3,514	4,075
	5,580	6,677
Less allowance for doubtful accounts and sales returns	480	460
	<u>\$ 5,100</u>	<u>\$ 6,217</u>

Note 4 — Inventories

Inventories consisted of the following at December 30, 2005 and December 31, 2004 (in thousands):

	<u>2005</u>	<u>2004</u>
Raw materials and purchased parts	\$ 859	\$ 985
Work in process	2,259	2,253
Finished goods	11,581	11,846
	<u>\$ 14,699</u>	<u>\$ 15,084</u>

Note 5 — Property, Plant and Equipment

Property, plant and equipment consisted of the following at December 30, 2005 and December 31, 2004 (in thousands):

	<u>2005</u>	<u>2004</u>
Machinery and equipment	\$ 12,174	\$ 12,388
Furniture and fixtures	5,498	4,378
Leasehold improvements	4,832	4,826
	22,504	21,592
Less accumulated depreciation and amortization	16,909	15,429
	<u>\$ 5,595</u>	<u>\$ 6,163</u>

Depreciation expense for each of the years ended December 30, 2005, December 31, 2004, and January 2, 2004 was approximately \$2.0 million.

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. Dividends received are recorded under the equity method as a reduction to the investment. The principal difference between 50% of the equity balance recorded on CSC's financial statements and the Company's recorded investment in the joint venture relates to the fiscal year 2000 write down of the investment of approximately \$3.6 million due to disputes between the Company and the Canon Companies. The disputes were subsequently resolved in late 2001.

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

The financial statements of CSC include the following information (in thousands):

	<u>2005</u>	<u>2004</u>
Current assets	\$ 5,679	\$ 6,237
Non-current assets	1,242	1,432
Current liabilities	1,025	1,238
Non-current liabilities	709	807
Net sales	9,656	10,908
Gross profit	5,171	4,572
Income from operations	460	220
Net Income (loss)	\$ 316	\$ (382)

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

	<u>2005</u>	<u>2004</u>	<u>2003</u>
Joint venture net income (loss)	\$ 316	\$ (382)	\$ 22
Equity interest	50%	50%	50%
Equity in earnings (loss) of joint venture	<u>\$ 158</u>	<u>\$ (191)</u>	<u>\$ 11</u>

The Company received dividends of \$0, \$81,000 and \$76,000 during 2005, 2004 and 2003, respectively.

The Company recorded sales of certain IOL products to CSC of approximately \$180,000, \$185,000 and \$66,000 in 2005, 2004 and 2003, respectively.

The Company purchased preloaded injectors from CSC in the amount of \$2.0 million, \$1.7 million, and \$239,000 in 2005, 2004, and 2003, respectively.

Note 7 — 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 3.25 million Swiss Francs "CHF" (approximately \$2.5 million based on the rate of exchange on December 30, 2005), and permits either fixed-term or current advances. The interest rate on current advances is 6.0% per annum at both December 30, 2005 and December 31, 2004, plus a commission rate of 0.25% payable quarterly. There were no current advances outstanding at December 30, 2005. The base interest rate for fixed-term advances follows Euromarket conditions for loans of a corresponding term and currency plus an individual margin (4.25% at December 30, 2005 and 4.5% at December 31, 2004, respectively). Borrowings outstanding under the note at December 30, 2005 and December 31, 2004, respectively, were CHF 2.2 million (approximately \$1.7 million based on the rate of exchange at December 30, 2005) and CHF 3.4 million (approximately \$3.0 million based on the rate of exchange on December 31, 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 inter-company 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 (\$2.3 million based on the exchange rate on December 30, 2005) and does not have a termination date; Part B presently provides for borrowings of up to CHF 250,000 (\$190,000 based on the exchange rate on December 30, 2005). The loan amount under Part B of the agreement reduces by CHF 250,000 (\$190,000 based on the

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

exchange rate on December 30, 2005) semi-annually. As of December 30, 2005, approximately \$824,000 was available under the credit facility for future borrowings for use in Swiss operations.

The German subsidiary entered into a new credit agreement on August 30, 2005. The renewed credit agreement provides for borrowings of up to 100,000 EUR (\$119,000 at the rate of exchange on December 30, 2005), at a rate of 7.0% per annum and does not have a termination date. The credit facility is not secured. There were no borrowings outstanding as of December 30, 2005 and December 31, 2004.

The Company was in compliance with the covenants of these credit facilities as of December 30, 2005.

Note 8 — Income Taxes

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

	<u>2005</u>	<u>2004</u>	<u>2003</u>
Current tax provision:			
U.S. federal	\$ —	\$ —	\$ —
State	18	—	—
Foreign	1,221	1,057	1,127
Total current provision	<u>1,239</u>	<u>1,057</u>	<u>1,127</u>
Deferred tax provision:			
U.S. federal and state	—	—	—
Foreign	—	—	—
Total deferred provision	<u>—</u>	<u>—</u>	<u>—</u>
Provision for income taxes	<u>\$ 1,239</u>	<u>\$ 1,057</u>	<u>\$ 1,127</u>

As of December 30, 2005, the Company had \$74.2 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 2025.

The Company has net income taxes payable at December 30, 2005 and December 31, 2004 of \$923,000 and \$420,000, respectively.

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

The provision 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):

	<u>2005</u>		<u>2004</u>		<u>2003</u>	
Computed benefit for taxes based on income at statutory rate	\$ (3,386)	34.0%	\$ (3,484)	34.0%	\$ (2,435)	34.0%
Increase (decrease) in taxes resulting from:						
Write down of investment in Circuit Tree Medical Inc.	—	—	—	—	715	(10.0)
Permanent differences	19	(0.2)	36	(0.3)	23	(0.3)
State taxes, net of federal income tax benefit	12	(0.1)	—	(0.0)	—	(0.0)
Tax effect attributed to foreign operations	300	(3.0)	158	(1.5)	107	(1.5)
Other	29	(0.3)	7	(0.1)	—	—
Valuation allowance	<u>4,265</u>	<u>(42.8)</u>	<u>4,340</u>	<u>(42.4)</u>	<u>2,717</u>	<u>(37.9)</u>
Effective tax provision rate	<u>\$ 1,239</u>	<u>(12.4)%</u>	<u>\$ 1,057</u>	<u>(10.3)%</u>	<u>\$ 1,127</u>	<u>(15.7)%</u>

The state tax provision is composed of an increase to the state deferred tax asset and corresponding increase to the valuation allowance of \$945,000, \$1,010,000, and \$386,000 for 2005, 2004 and 2003 respectively. This results in a total state tax provision of \$18,000, for 2005 and zero state tax provision for 2004 and 2003.

Undistributed earnings of the Company's foreign subsidiaries amounted to approximately \$13.1 million at December 30, 2005. 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.

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 30, 2005 and December 31, 2004 are as follows (in thousands):

	<u>2005</u>	<u>2004</u>
Current deferred tax assets (liabilities):		
Allowance for doubtful accounts and sales returns	\$ 133	\$ 143
Inventory	663	475
Accrued vacation	260	171
State taxes	3	3
Deferred revenue	46	79
Accrued expenses	—	21
Valuation allowance	(1,105)	(892)
Total current deferred tax assets (liabilities)	<u>\$ —</u>	<u>\$ —</u>
Non-current deferred tax assets (liabilities):		
Net operating loss and capital loss carryforwards	30,157	25,508
Business, foreign and AMT credit carryforwards	880	880
Depreciation and amortization	28	(54)
Notes receivable	517	207
Restructuring — investment in joint venture	511	450
Capitalized R&D	420	252
Contributions	44	37
Valuation allowance	(32,557)	(27,280)
Total non-current deferred tax assets (liabilities)	<u>\$ —</u>	<u>\$ —</u>

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. Due to its history of losses, the Company records a valuation allowance to fully offset the value of its deferred tax assets. Further, under Federal Tax Law Internal Revenue Code Section 382, significant changes in ownership may restrict the future utilization of these tax loss carry forwards.

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

	<u>2005</u>	<u>2004</u>	<u>2003</u>
Domestic	\$ (12,665)	\$ (12,887)	\$ (10,163)
Foreign	2,707	2,641	3,001
	<u>\$ (9,958)</u>	<u>\$ (10,246)</u>	<u>\$ (7,162)</u>

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

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

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.

Note 10 — Stockholders' Equity

Common Stock

During fiscal year 2005, the Company issued 13,000 shares to consultants for services rendered to the Company. Also during 2005, the Company completed a private placement with institutional investors of 4,100,000 shares of the Company's common stock, for net proceeds of \$13.4 million. Also during 2005, the Company issued 6,117 shares of restricted stock to certain employees and a consultant in consideration for future services to the Company. The shares were issued at fair market value on the date of grant, vest over a period of three years, and are subject to forfeiture until vested or the service period is terminated. The cost of the restricted stock is recorded as deferred equity compensation in Additional Paid-in Capital and will be amortized over the vesting period. As of December 30, 2005, none of the shares were vested.

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 2,000,000 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 1,000,000 shares of the Company's common stock, for net proceeds of \$8.9 million.

Receivables from Former Directors

As of December 30, 2005 and December 31, 2004, notes receivable (excluding reserves) from former directors totaling \$2.0 million and \$2.1 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 mature on various dates through July 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 a \$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 30, 2005, the Company recorded additional reserves of \$746,000 against promissory notes of a former director of the Company. Aggregate principal and accrued interest owed to the Company under the notes was \$1.9 million as of December 30, 2005, against which the Company has reserved a total of \$1.2 million. The former director is in default under the notes and a related Forbearance Agreement with the Company, but has recently affirmed his obligation under the notes. On these events, the Company re-evaluated its likelihood of collecting on the notes and re-examined the collateral for the notes, which consists of a pledge of 120,000 shares of the Company's Common Stock (the "Pledged Shares") and a second mortgage on a home in Florida. During the third quarter of 2005, the Company was advised that its collateral may be compromised with respect to the second mortgage. Accordingly, the Company increased its reserve on the notes to reflect the status of the collateral. Notwithstanding the additional reserve amount, the Company believes that the former director is obligated to repay the full amount of principal and interest on the notes, and continues to pursue full repayment of the notes.

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

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 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 granted	1,044	\$ 4.40
Options exercised	(36)	\$ 3.65
Options forfeited/cancelled	(290)	\$ 9.55
Balance at December 30, 2005	3,870	\$ 6.23
Options exercisable at December 30, 2005	2,728	\$ 6.77
Options exercisable at December 31, 2004	2,535	\$ 7.27
Options exercisable at January 2, 2004	2,541	\$ 7.44

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 date of grant, become exercisable over a 3-4 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 1,508,000, 522,000 and 83,000 shares were outstanding at December 30, 2005, December 31, 2004 and January 2, 2004, respectively, with exercise prices ranging between \$3.70 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 30, 2005, December 31, 2004, and January 2, 2004, 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

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

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 1,441,000, 1,601,000, and 1,855,000 shares were outstanding at December 30, 2005, December 31, 2004, and January 2, 2004, respectively, with exercise prices ranging between \$2.05 and \$13.625 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 141,000, 146,000, and 146,000 shares were outstanding at December 30, 2005, December 31, 2004, and January 2, 2004, respectively. The options were originally issued with an exercise price of \$12.50 per share. During fiscal year 1998 the exercise price of options held by employees 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, 165,000, and 330,000 shares were outstanding at December 30, 2005, December 31, 2004, and January 2, 2004, 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. Pursuant to this plan, options for 60,000, 163,000 and 220,000 shares were outstanding at December 30, 2005, December 31, 2004, and January 2, 2004, respectively, with exercise prices ranging from \$9.56 to \$10.18 per share.

During fiscal years 1999 and 2000, the Company issued non-qualified options to purchase shares of its Common Stock to employees and consultants. Pursuant to these agreements, options for 55,000, 55,000, and 85,000 shares were outstanding at December 30, 2005, December 31, 2004, and January 2, 2004, respectively with exercise prices ranging between \$9.375 and \$10.63.

In fiscal year 2005, officers, employees and others exercised 36,000 options from the 1998 and 2003 stock option plans at prices ranging from \$2.00 to \$4.62 resulting in cash proceeds totaling \$130,000.

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.

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

The following table summarizes information about stock options outstanding and exercisable at December 30, 2005 (in thousands, except per share data):

Range of Exercise Prices	Number Outstanding at 12/30/05	Options Outstanding Weighted-Average		Number Exercisable at 12/30/05	Weighted-Average Exercise Price
		Remaining Contractual Life	Weighted-Average Exercise Price		
\$ 1.70 to \$ 2.15	149	2.3 years	\$ 1.91	149	\$ 1.91
\$ 2.96 to \$ 4.30	1,788	5.6 years	\$ 3.70	1,060	\$ 3.56
\$ 4.62 to \$ 6.54	621	5.0 years	\$ 5.71	395	\$ 5.69
\$ 7.00 to \$10.19	471	6.4 years	\$ 8.53	300	\$ 8.96
\$10.60 to \$13.63	<u>841</u>	4.8 years	<u>\$ 11.48</u>	824	<u>\$ 11.49</u>
\$ 1.70 to \$13.88	<u>3,870</u>	5.3 years	<u>\$ 6.23</u>	2,728	<u>\$ 6.77</u>

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 30, 2005 were approximately as follows (in thousands):

Fiscal Year	Operating Leases	Capital Leases
2006	\$ 1,179	\$ 51
2007	596	48
2008	500	77
2009	390	1
2010	<u>365</u>	<u>—</u>
Total minimum lease payments	\$ 3,030	\$ 177
Less amounts representing interest	<u>—</u>	<u>(25)</u>
	<u>\$ 3,030</u>	<u>\$ 152</u>
Current		\$ 36
Long-term		<u>116</u>
Total		<u>\$ 152</u>

Rent expense was approximately \$1.2 million for each of the years ended December 30, 2005, December 31, 2004, and January 2, 2004, respectively.

Supply Agreement

In December 2000, the Company entered into a minimum purchase agreement with another manufacturer for the purchase of viscoelastic solution. In January 2006, the Company extended this agreement through December 31, 2008 under the same purchasing terms as the original contract. 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

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

regulatory approval of the product in other markets, excluding the U.S and Canada, as requested by the Company. Purchases under the agreement for fiscal 2005, 2004, and 2003 were approximately \$728,000, \$644,000, and \$954,000, respectively.

As of December 30, 2005, estimated annual purchase commitments under this contract are as follows (in thousands):

<u>Fiscal Year</u>	
2006	\$ 600
2007	600
2008	894
	<u>\$ 2,094</u>

Resolution of Open Issues with the FDA Office of Compliance

The Office of Compliance of the FDA's Center for Devices and Radiological Health regularly inspects STAAR's facilities to determine whether STAAR is in compliance with the FDA's Quality System Regulations relating to such things as manufacturing practices, validation, testing, quality control, product labeling and complaint handling, and in compliance with FDA Medical Device Reporting regulations.

Failure to demonstrate substantial compliance with these regulations and can result in enforcement actions that terminate, suspend or severely restrict the ability to continue manufacturing and selling medical devices.

After an inspection of STAAR's Monrovia, California facility in August and September of 2003, STAAR received Form 483 Inspectional Observations, Warning Letters, and other correspondence from the FDA's Office of Compliance indicating that the FDA deemed STAAR's Monrovia, California facility to be violating the FDA's Quality System Regulations and Medical Device Reporting regulations. In a Warning Letter received on December 29, 2003 the FDA warned of possible enforcement action and stated that it would not approve premarket applications for the approval of Class III devices (such as the ICL) until related violations of the Quality System Regulation were corrected. These violations were last asserted by the FDA in a letter received on July 5, 2005, which stated that the agency found STAAR's earlier responses inadequate.

STAAR responded to the FDA's observations and assertions by implementing numerous improvements to its quality system in consultation with the agency and independent consultants. Among other things, STAAR developed a Global Quality Systems Action Plan, which has been continuously updated since its adoption in April, 2004, and took steps to emphasize a focus on compliance throughout the organization.

In 2005, STAAR undertook a compliance initiative that included a comprehensive revision of its operating procedures to ensure alignment with all FDA regulations and the international ISO 13485 standard, training to implement the new procedures and enhance its internal audit function to provide for self-regulation by verifying compliance and ensuring corrective action for noncompliance.

The FDA Office of Compliance conducted its most recent inspection of STAAR's Monrovia, California facility between August 29, 2005 and September 14, 2005. At the conclusion of the inspection the inspectors issued three Inspectional Observations on FDA Form 483. One of the observations was annotated as "corrected and verified," and the Company promised to correct the remaining two. The Company provided details of its corrective actions on the remaining two observations to the FDA by letter on October 11, 2005.

On November 18, 2005, in response to a request by STAAR, STAAR received from the FDA certificates that may be provided to foreign governments (the "Certificates") to permit the importation into foreign countries of STAAR products manufactured at its facility in Monrovia, California. In the Certificates, the FDA certified that during the FDA's last inspection STAAR's Monrovia manufacturing facility appeared to be in substantial

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

compliance with current good manufacturing practice requirements for the products listed on the Certificates. The listed products include all of the products then manufactured and sold in the U.S. by STAAR.

On December 22, 2005, the FDA Office of Device Evaluation notified STAAR that its pre-market approval application for the VISIAN ICL was approved.

Based on the results of the re-inspection concluded on September 14, 2005, the issuance of the Certificates on November 18, 2005, and the FDA's final approval of the VISIAN ICL on December 22, 2005, STAAR believes that it has resolved the compliance issues previously identified by the FDA and has demonstrated that it is now substantially in compliance with the FDA's Quality System Regulations and Medical Device Reporting regulations.

Nevertheless, the FDA's findings of compliance deficiencies during the preceding two years have harmed STAAR's reputation in the ophthalmic industry and affected its product sales, and delayed FDA approval of the ICL. STAAR's ability to continue its U.S. business depends on the continuous improvement of its quality systems and its ability to demonstrate substantial compliance with FDA regulations. Accordingly, for the foreseeable future STAAR's management expects its strategy to include devoting significant resources and attention to those efforts.

Indemnification Agreements

The Company has entered into indemnification agreements with its directors and officers that may require the Company: a) 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; b) to advance their expenses incurred as a result of any proceeding against them as to which they could be indemnified; and c) 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

In re STAAR Surgical Co. Securities Litigation, No. CV 04-8007. The Company and its Chief Executive Officer are defendants in a class action lawsuit pending in the Central District of California. A consolidated amended complaint filed by the plaintiffs on April 29, 2005 generally alleges 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 the prospects for FDA approval of STAAR's VISIAN ICL, thereby artificially inflating the price of the Company's Common Stock. The plaintiffs generally seek to recover compensatory damages, including interest.

The defendants filed a motion to dismiss, which the court denied in an order filed September 19, 2005 (the "Order"). While permitting the case to proceed, the Order effectively narrowed the proposed class to purchasers of the Company's securities between October 6, 2003 and January 5, 2004 by limiting the statements of the defendants that the plaintiffs may challenge.

On December 27, 2005, a Joint Status Report and Notice of Settlement (the "Notice") was filed with the court, indicating that the parties had reached an agreement to settle all claims. In the Notice, the parties to the Class Action Lawsuit informed the Court that they have reached an agreement to resolve the litigation, without admission of liability, and have signed a Memorandum of Understanding. The effectiveness of the agreement among the parties is subject to the parties' negotiating and approving the terms of a Stipulation of Settlement, and to the Court's final approval, after notice to the Class, of the terms set forth in that Stipulation.

The Memorandum of Understanding provides, among other things, that in consideration of their agreement to settle the Company will pay to the plaintiffs total consideration of \$3,700,000. The Company's insurance carrier has represented that the proceeds of insurance will cover those payments and all other costs related to

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

settlement of the Class Action Lawsuit, except for approximately \$100,000 in administrative costs payable, accrued at December 30, 2005 by the Company as part of its retention under the terms of its insurance policy.

The Stipulation of Settlement remains under negotiation among the parties. The Class Action Lawsuit remains pending until the Stipulation of Settlement is executed and filed by the parties and finally approved by the court.

From time to time the Company is subject 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 the Company does not believe that any of the claims known is likely to have a material adverse effect on its 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 30, 2005 and December 31, 2004 are approximately \$1,934,000 and \$1,868,000 of accrued salaries and wages and \$654,000 and \$808,000 of commissions due to outside sales representatives, respectively.

Note 13 — Related Party Transactions

The Company has had significant related party transactions as discussed in Notes 6, 9, 10, and 15.

In addition to secured notes (see Note 10), the Company holds other various promissory notes from employees 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 employees and included in prepaids, deposits, and other current assets at December 30, 2005 and December 31, 2004 were \$110,000 and \$104,000, respectively.

The Company paid a Board member for consulting services related to strategic marketing in the ophthalmic sector. Amounts paid during the year ended December 30, 2005, December 31, 2004, and January 2, 2004, were \$2,000, \$13,000, and \$50,000, respectively.

Note 14 — Supplemental Disclosure of Cash Flow Information

Interest paid was \$181,000, \$159,000 and \$255,000 for the years ended December 30, 2005, December 31, 2004, and January 2, 2004, respectively. Income taxes paid amounted to approximately \$1,047,000, \$1,602,000 and \$1,477,000 for the years ended December 30, 2005, December 31, 2004, and January 2, 2004, respectively. Income taxes paid in fiscal 2003 were partially offset by the receipt of \$962,000 in U.S. federal tax refunds related to a carryback claim filed in fiscal 2002.

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

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

	<u>2005</u>	<u>2004</u>	<u>2003</u>
Non-cash investing activities:			
Purchase of fixed assets on terms	\$ 200	\$ —	\$ —
Non-cash financing activities:			
Notes receivable reserve	746	500	1,713
Other charges	(746)	(500)	(1,713)
Acquisition of business:			
Minority interest acquired	\$ —	\$ 203	\$ —
Goodwill	—	1,107	—
Note payable	—	(542)	—
Cash paid	—	(768)	—
Patent impairment:			
Patents	\$ —	\$ —	\$ (2,438)
Accumulated amortization	—	—	336
Other charges	—	—	2,102

Note 15 — Other Charges

During fiscal 2005 and fiscal 2004, the Company recorded reserves totaling \$746,000 and \$500,000, respectively, against promissory notes of a former director of the Company. Aggregate principal and accrued interest owed to the Company under the notes was \$1.9 million as of December 30, 2005, against which the Company has reserved a total of \$1.2 million. The former Director is in default under the notes and a related Forbearance Agreement with the Company, but has recently affirmed his obligation under the notes.

On these events, the Company re-evaluated its likelihood of collecting on the notes and re-examined the collateral for the notes, which consists of a pledge of 120,000 shares of the Company's Common Stock (the "Pledged Shares") and a second mortgage on a home in Florida. During the third quarter of 2005, the Company was advised that its collateral may be compromised with respect to the second mortgage. Accordingly, the Company increased its reserve on the notes to reflect the status of the collateral.

Notwithstanding the additional reserve amount, the Company believes the former director is obligated to repay the full amount of principal and interest on the notes, and continues to pursue full repayment of the notes.

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 former officers and directors which the Company has settled.

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

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):

	<u>2005</u>	<u>2004</u>	<u>2003</u>
Basic weighted average shares outstanding	23,704	19,602	17,704
Diluted effect of stock options and warrants	<u>—</u>	<u>—</u>	<u>—</u>
Diluted weighted average shares outstanding	<u>23,704</u>	<u>19,602</u>	<u>17,704</u>

Note 17 — Geographic and Product Data

The Company markets and sells its products in over 42 countries and has manufacturing sites in the United States and Switzerland. Other than the United States, Germany and Australia, 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, Australia, and other locations for each year, is set forth below (in thousands):

	<u>2005</u>	<u>2004</u>	<u>2003</u>
Sales to unaffiliated customers			
U.S.	\$ 18,715	\$ 21,643	\$ 23,464
Germany	22,433	22,128	19,840
Australia	2,722	1,914	1,522
Other	7,433	6,000	5,583
Total	<u>\$ 51,303</u>	<u>\$ 51,685</u>	<u>\$ 50,409</u>

100% of the Company's sales are generated from the ophthalmic surgical product segment and, therefore, the Company operates as one operating segment for financial reporting purposes. The Company's principal products are IOLs and ancillary products used in cataract and refractive surgery. The composition of the Company's net sales by surgical line are as follows (in thousands):

Net Sales by Surgical Line

	<u>2005</u>	<u>2004</u>	<u>2003</u>
Cataract	\$ 45,361	\$ 46,772	\$ 46,409
Refractive	5,288	4,066	3,050
Glaucoma	654	847	950
Total	<u>\$ 51,303</u>	<u>\$ 51,685</u>	<u>\$ 50,409</u>

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

The composition of the Company's long-lived assets, consisting of property and equipment, patents and licences, and goodwill, between those in the United States, Germany, Switzerland, and other countries is set forth below (in thousands):

	<u>2005</u>	<u>2004</u>
Long-lived assets		
U.S.	\$ 8,072	\$ 9,035
Germany	6,952	6,799
Switzerland	1,646	2,010
Australia	1,379	1,253
Total	<u>\$ 18,049</u>	<u>\$ 19,097</u>

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 2005 and 2004 is as follows (in thousands except per share data):

<u>December 30, 2005</u>	<u>1st Qtr.</u>	<u>2nd Qtr.</u>	<u>3rd Qtr.</u>	<u>4th Qtr.</u>
Revenues	\$ 13,678	\$ 13,910	\$ 11,647	\$ 12,068
Gross profit	6,450	6,610	5,197	5,529
Net loss	(2,338)	(2,110)	(3,302)	(3,425)
Basic and diluted loss per share	(.11)	(.09)	(.13)	(.14)

<u>December 31, 2004</u>	<u>1st Qtr.</u>	<u>2nd Qtr.</u>	<u>3rd Qtr.</u>	<u>4th Qtr.</u>
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)

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.

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

INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM
REPORT ON SCHEDULE

To the Board of Directors
STAAR Surgical Company
Monrovia, CA

The audits referred to in our report dated March 15, 2006 relating to the consolidated financial statements of STAAR Surgical Company and Subsidiaries, which is contained in Item 8 of this Form 10-K included the audit of Schedule II, Valuation and Qualifying Accounts and Reserves as of December 30, 2005, and for each of the three years in the period ended December 30, 2005. 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 audits.

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 15, 2006

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

<u>Column A</u>	<u>Column B</u>	<u>Column C</u>	<u>Column D</u>	<u>Column E</u>
<u>Description</u>	<u>Balance at Beginning of Year</u>	<u>Additions</u>	<u>Deductions</u>	<u>Balance at End of Year</u>
	(In thousands)			
2005				
Allowance for doubtful accounts and sales returns deducted from accounts receivable in balance sheet	\$ 460	\$ 191	\$ 171	\$ 480
Deferred tax asset valuation allowance	28,172	5,490	—	33,662
Notes receivable reserve	500	746	—	1,246
	<u>\$ 29,132</u>	<u>\$ 6,427</u>	<u>\$ 171</u>	<u>\$ 35,388</u>
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
	<u>\$ 22,809</u>	<u>\$ 6,833</u>	<u>\$ 510</u>	<u>\$ 29,132</u>
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	1,796	—	1,796	—
	<u>\$ 21,208</u>	<u>\$ 3,576</u>	<u>\$ 1,975</u>	<u>\$ 22,809</u>

INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM'S CONSENT

STAAR Surgical Company
Monrovia, CA

We hereby consent to the incorporation by reference in the Registration Statements on Forms S-8 No. 333-111154 and No. 333-60241 and Forms S-3 No. 333-124022, No. 333-116901, No. 333-111140, No. 333-106989, and No. 333-124022 of STAAR Surgical Company of our reports dated March 15, 2006, relating to the consolidated financial statements and the effectiveness of STAAR Surgical Company's internal control over financial reporting, which appear in this Form 10-K. We also consent to the incorporation by reference of our report dated March 15, 2006 relating to the financial statement schedule which appears in this Form 10-K.

/s/ BDO SEIDMAN, LLP

Los Angeles, California
March 15, 2006

CERTIFICATIONS

I, David Bailey, Chief Executive Officer, certify that:

1. I have reviewed this annual report on Form 10-K of STAAR Surgical Company;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 15, 2006

By: /s/ DAVID BAILEY
David Bailey
*President, Chief Executive Officer and
Director (principal executive officer)*

CERTIFICATIONS

I, Deborah Andrews, Chief Financial Officer, certify that:

1. I have reviewed this annual report on Form 10-K of STAAR Surgical Company;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 15, 2006

By: /s/ DEBORAH ANDREWS
Deborah Andrews
Chief Financial Officer
(principal accounting and financial officer)

**Certification pursuant to 18 U.S.C. Section 1350,
As adopted pursuant to Section 906 of the Sarbanes–Oxley Act of 2002**

In connection with the filing of the Annual Report on Form 10–K for the year ended December 30, 2005 (the “Report”) by STAAR Surgical Company (“Registrant”), each of the undersigned hereby certifies that:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of Registrant as of and for the periods presented in the Report.

Dated: March 15, 2006

By: /s/ DAVID BAILEY
David Bailey
President, Chief Executive Officer and Director
(principal executive officer)

Dated: March 15, 2006

By: /s/ DEBORAH ANDREWS
Deborah Andrews
Chief Financial Officer (principal
accounting and financial officer)

A signed original of this written statement required by Section 906 has been provided to STAAR Surgical Company and will be furnished to the Securities and Exchange Commission or its staff upon request.