

STAAR SURGICAL CO
Form 10-K
March 29, 2007

Table of Contents

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

Form 10-K

(Mark One)

- b** ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES
EXCHANGE ACT OF 1934
For the fiscal year ended December 29, 2006
- or**
- o** TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES
EXCHANGE ACT OF 1934
For the transition period from to

Commission file number: 0-11634

STAAR SURGICAL COMPANY

(Exact name of registrant as specified in its charter)

Delaware
*(State or other jurisdiction of
incorporation or organization)*

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

**1911 Walker Avenue 91016
Monrovia, California**
(Address of principal executive offices)

(626) 303-7902
Registrant's telephone number, including area code

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

(Title of each class)	(Name of each exchange on which registered)
Common Stock, \$0.01 par value	Nasdaq Global Market

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

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 June 30, 2006, the last business day of the registrant's most recently completed second fiscal quarter, was approximately \$195,393,000 based on the closing price per share of \$7.74 of the registrant's Common Stock on that date.

The number of shares outstanding of the registrant's Common Stock as of March 23, 2007 was 25,678,183.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement relating to its 2007 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

	Page
<u>PART I</u>	
<u>Item 1.</u> <u>Business</u>	2
<u>Item 1A.</u> <u>Risk Factors</u>	12
<u>Item 1B.</u> <u>Unresolved Staff Comments</u>	22
<u>Item 2.</u> <u>Properties</u>	22
<u>Item 3.</u> <u>Legal Proceedings</u>	22
<u>Item 4.</u> <u>Submission of Matters to a Vote of Security Holders</u>	22
<u>PART II</u>	
<u>Item 5.</u> <u>Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u>	22
<u>Item 6.</u> <u>Selected Financial Data</u>	24
<u>Item 7.</u> <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	25
<u>Item 7A.</u> <u>Quantitative and Qualitative Disclosures About Market Risk</u>	43
<u>Item 8.</u> <u>Financial Statements and Supplementary Data</u>	44
<u>Item 9.</u> <u>Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</u>	44
<u>Item 9A.</u> <u>Controls and Procedures</u>	44
<u>Item 9B.</u> <u>Other Information</u>	46
<u>PART III</u>	
<u>Item 10.</u> <u>Directors, Executive Officers and Corporate Governance</u>	47
<u>Item 11.</u> <u>Executive Compensation</u>	47
<u>Item 12.</u> <u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	47
<u>Item 13.</u> <u>Certain Relationships and Related Transactions, and Director Independence</u>	47
<u>Item 14.</u> <u>Principal Accountant Fees and Services</u>	47
<u>PART IV</u>	
<u>Item 15.</u> <u>Exhibits and Financial Statement Schedules</u>	47
<u>Signatures</u>	52
<u>EXHIBIT 23.1</u>	
<u>EXHIBIT 31.1</u>	
<u>EXHIBIT 31.2</u>	
<u>EXHIBIT 32.1</u>	

Table of Contents

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 a forecast 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 minimally invasive 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.

STAAR Surgical Company, Visian[™], Collamer[®], STAARVISC[®], Elastimide[®], SonicWAVE[™] and AquaFlow[™] are trademarks or registered trademarks of STAAR in the U.S. and other countries. Collamer[®] is the brand name for STAAR's proprietary collagen copolymer lens material.

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 preexisting 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, which 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 VisiO[®] 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 more than 40 countries. The Company's goal is to establish the ICL and TICL worldwide as a primary choice for refractive surgery, making the products increasingly significant revenue generators for the Company.

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

Table of Contents

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. The ICL is also approved in China where an application for the TICL is pending. Applications are also pending in Australia, and the Company is working to obtain new approvals for the ICL and TICL in other countries. The Company submitted its application for U.S. approval of the TICL to the FDA in 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. Among 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 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 more than 40 countries and has been implanted in more than 65,000 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 preexisting astigmatism. 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 16 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 46% of our total revenues for the 2006 fiscal year, 52% of total revenues for the 2005 fiscal year and 56% of total revenues for the 2004 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 approximately 31%

Table of Contents

of our total revenues for the 2006 fiscal year, 36% of total revenues for the 2005 fiscal year and 32% of total revenues for the 2004 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 submitted its application for U.S. approval of the TICL to the FDA in 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 four lengths, with 41 powers for each length, and for hyperopia in four lengths, with 37 powers for each length, which equates to 420 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 generally made to order.

Sales of ICLs (including TICLs) accounted for approximately 22% of our total revenues for the 2006 fiscal year, 10% of total revenues for the 2005 fiscal year and 8% of total revenues for the 2004 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's established customers for the AquaFlow device continue to implant the product, 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

Table of Contents

or new product designs to simplify the implantation procedure. Sales of AquaFlow devices accounted for approximately 1% of our total revenues in 2006, 1% of our total revenues in 2005, and 2% of our total revenues 2004.

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 29, 2006, we owned approximately 104 United States and foreign patents and had approximately 42 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 may also be able to maintain exclusivity by patenting important improvements to the products. We routinely monitor the activities of our competitors and other third parties with respect to their use of intellectual property, including considering

whether or not to assert our patents where we believe they are being infringed.

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

Table of Contents

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, Germany and Australia. Sales efforts in Germany and Australia are primarily supported through a direct sales force. In the United States we sell through a network of independent manufacturers' representatives in some regions and sell through a direct sales force in other regions. We compensate the independent representatives through sales commissions and compensate direct sales staff through a combination of salary and commissions. Our independent manufacturers' representatives 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 2006 Market Scope report, Alcon holds 54% of the U.S. IOL market, followed by AMO with 26% and Bausch & Lomb with 14%. We hold approximately 4% 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 62% share of the U.S. IOL market. We believe that we are positioned to compete effectively in the advanced material market segment with the Collamer IOL. We plan to introduce enhanced models of the Collamer IOL and improved injectors which we believe can strengthen our position and help reverse the decline in our overall IOL market share. Although the market for Silicone IOLs, which currently account for 34% of the U.S. market, has declined in recent years, we

Table of Contents

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 Visiantm 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

Table of Contents

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. Our activities as a sponsor of clinical research are subject to review by the Bioresearch Monitoring Program of the FDA Office of Regulatory Affairs, known as BIMO.

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 Conformite Europeane Mark (CE Mark). The CE Mark denotes that the applicable medical device has been found to be in compliance with the respective European Directives and associated 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 2007), 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 submitted a supplemental pre-market approval application for the TICL in April 2006, and is preparing an amendment to the application in response to comments from the FDA Office of Device Evaluation. The Company is also conducting clinical trials on the hyperopic ICL for the U.S. market.

Table of Contents

Recent Proceedings With the FDA Office of Compliance

Based on the results of the FDA inspections of STAAR's Monrovia, California facilities in 2005 and 2006, 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. STAAR responded to the FDA's observations and assertions by, among other things, comprehensively revising its quality-related operating procedures, training to implement the revised procedures, and enhancing its internal quality audit function to provide for self-regulation by verifying compliance and ensuring corrective action for noncompliance. Notwithstanding the substantial improvement in STAAR's compliance and quality, the FDA's past findings of compliance deficiencies harmed our reputation in the ophthalmic industry, 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.

STAAR's activities as a sponsor of biomedical research are subject to review by the Bioresearch Monitoring Program of the FDA Office of Regulatory Affairs (BIMO). On March 14, 2007, BIMO concluded a routine audit of the Company's clinical trial records as a sponsor of biomedical research in connection with the Company's Supplemental Pre-Market Approval application for the Toric ICL (TICL). At the conclusion of the audit the Company received eight Inspectional Observations on FDA Form 483 noting noncompliance with regulations. The Company is preparing its response to the Inspectional Observations and expects to address the concerns raised by BIMO through voluntary corrective actions. Most of the observed instances of non-compliance took place during the 2000-2004 period and the Company expects to show that some of these have already been addressed by corrective actions made in response to BIMO's observations of December 11, 2003 in connection with the Company's application for the ICL.

The Company does not believe that the Inspectional Observations affect the integrity of the Toric clinical study. However, the determination of whether the Inspectional Observations affect the use of the Toric clinical study in the Toric application will be at the discretion of the FDA Office of Device Evaluation (ODE). Obtaining FDA approval of medical devices is never certain. The Company cannot assure investors that the ODE will grant approval to the TICL, or that the scope of requested TICL approval could not be limited by the FDA or the Ophthalmic Devices Panel.

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 29 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, and expect to continue to focus in 2007, our research and development efforts on the following:

Development of a Collamer Toric IOL to complement our pioneering silicone Toric IOL;

Development of a new three-piece Collamer IOL featuring an aspheric optic design;

Development of new silicone IOL models featuring aspheric optics and a squared edge configuration;

Enhancements to the injector system for our three-piece Collamer IOL to improve delivery, and development of an all new injector system for the three-piece Collamer IOL;

Development of a micro-incision injector for the one-piece Collamer IOL;

Development of a preloaded injector system for our new silicone aspheric IOLs; and

Table of Contents

Supporting the application for U.S. approval of the Toric ICL.

Research and development expenses were approximately \$7,080,000, \$5,573,000, and \$6,246,000 for our 2006, 2005 and 2004 fiscal years, respectively. STAAR expects to pay a similar amount for research and development in 2007.

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 German 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 Marketing Japan 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 Marketing, 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 Marketing 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.

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 Marketing is to enter into a distribution agreement with the joint venture providing a minimum 50-70% share of sales revenue

Table of Contents

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 March 23, 2007, we employed approximately 284 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 several fiscal years and have an accumulated deficit of \$86.7 million as of December 29, 2006. There can be no assurance that we will report net income in any future period.

We have only limited working capital and limited access to financing.

While STAAR has experienced increased sales in recent periods, our cash requirements continue to exceed the level of cash generated by operations and we expect to continue to seek additional resources to support and expand our business, such as debt or equity financing. Because of our history of losses and negative cash flows, our ability to obtain adequate financing on satisfactory terms is limited. Our ability to raise financing through sales of equity securities depends on general market conditions and the demand for STAAR's common stock. We may be unable to raise adequate capital through sales of equity securities, and if our stock has a low market price at the time of such

Table of Contents

sales our existing stockholders could experience substantial dilution. An inability to secure additional financing could limit the expansion of our business and jeopardize our ability to continue operations.

Our history of losses limits our access to credit and increases the risk of a default on our loan agreements.

Under its U.S. and international bank credit facilities and lease lines of credit, STAAR had \$3 million in outstanding indebtedness and \$1.4 million available for borrowing as of December 29, 2006. The credit facilities are subject to various financial covenants, and if our losses continue we risk defaulting on the terms of our credit facilities. Our limited borrowing capacity could cause a shortfall in working capital or prevent us from making expenditures to expand or enhance our business. To the extent we borrow under our credit facilities, a subsequent default could cause our obligations to be accelerated, make further borrowing difficult and jeopardize our ability to continue operations.

We may be subject to limitations in fully utilizing our recorded tax loss carryforwards.

We have accumulated approximately \$37.4 million of tax carryforwards to be used in future periods. If we were to experience a significant change in ownership, Internal Revenue Code Section 382 may restrict the future utilization of these tax loss carry forwards.

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 the FDA inspections of STAAR's Monrovia, California facilities in 2005 and 2006, 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 we received Warning Letters and other correspondence indicating that the FDA found STAAR's Monrovia, California facility in violation of applicable regulations, warning of possible enforcement action and suspending approval of new implantable devices. The FDA's findings of compliance deficiencies during that period harmed our reputation in the ophthalmic industry, 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 its efforts will always be successful, and any failure to demonstrate substantial compliance with FDA regulations can result in enforcement actions that terminate, suspend or severely restrict our ability to continue manufacturing and selling medical devices. Please see the related risks discussed under the headings *We are subject to extensive government regulation, which increases our costs and could prevent us from selling our products* and *We are subject to federal and state regulatory investigations*.

Our strategy to restore profitability in the near term relies on successfully penetrating the U.S. refractive market.

While products to treat cataracts continue to account for the majority of our revenue, we believe that increasing sales of our Visian® ICL refractive products, especially in the U.S., present the best near term opportunity for a return to profitability. The FDA approved the Visian ICL for treatment of myopia on December 22, 2005. Selling and marketing the ICL has presented a challenge to our sales and marketing staff and to our independent manufacturers

representatives. In the United States 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. In addition, established refractive surgeons frequently have large and well developed practices that are oriented entirely toward the delivery of laser procedures. In countries where the ICL has been approved to date, our

Table of Contents

sales have grown steadily but slowly, and the U.S. appears to be following this pattern. A surgeon interested in implanting the ICL must first schedule training and certification and invest time in the training process. While STAAR has sufficient resources to make training available to qualified surgeons with minimal delay, the need to undergo training continues to limit the pace at which interested surgeons can begin providing the ICL to their patients. STAAR employs advertising and promotion targeted to potential patients through providers, but has limited resources for these purposes. Failure to successfully market the ICL in the United States will delay and possibly prevent our planned growth and return to profitability.

Our core domestic business has suffered declining sales, which sales of new products have only begun to 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 addition, our competitors have begun to offer multifocal or accommodating lenses that claim to reduce the need for cataract patients to use reading glasses; the market for these presbyopic lenses is expected to grow as a segment of the cataract market. Our newer line of IOLs made of our proprietary biocompatible Collamer® material have helped reverse the trend of declining domestic cataract product sales, but it is too early to assess the potential for sustained growth and whether we can recover a significant amount of the market share lost over the last several years.

Strikes, slow-downs or other job actions by doctors can reduce sales of cataract-related products.

In many countries where STAAR sells its products, doctors, including ophthalmologists, are employees of the government, government-sponsored enterprises or large health maintenance organizations. In recent years employed doctors who object to salary limitations, working rules, reimbursement policies or other conditions have sought redress through strikes, slow-downs and other job actions. These actions often result in the deferral of non-essential procedures, such as cataract surgeries, which can affect sales of our products. For example, in fiscal year 2006, strikes and slow-downs by doctors in Germany were partly responsible for a drop in sales by our wholly owned subsidiary Domilens GmbH, which distributes ophthalmic products in Germany. Such problems could occur again in Germany or other regions and, depending on the importance of the affected region to STAAR's business, the length of the action and its pervasiveness, job actions by doctors can materially reduce our sales revenue and earnings.

Because state-sponsored healthcare systems, health maintenance organizations and insurance reimbursement usually do not cover refractive surgery, job actions by doctors are unlikely to affect ICL sales.

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. STAAR's strategy for growth involves the marketing of innovative products like the ICL, Collamer IOLs, Toric IOLs and the AquaFlow Device. We have relied on the

Table of Contents

independent representatives to implement the marketing of these products and to sustain the market for our more established products. Because our independent representatives generally have little experience dealing with surgeons who specialize in refractive procedures, we have faced greater challenges in developing the domestic market for 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 the manufacturer's recall for possible endotoxin content. In 2005, we recalled one lot of phaco tubing manufactured by a third party, due to incorrect labeling, 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. The last recall of STAAR products took place during 2004, when 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

Table of Contents

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 29, 2006, sales from international operations were 60% 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.

The success of our international operations depends on our successfully managing our foreign subsidiaries.

We conduct most of our international business through wholly owned subsidiaries. Managing distant subsidiaries and fully integrating them into STAAR's business is challenging. While STAAR seeks to fully integrate its foreign subsidiaries into its operations, direct supervision of every aspect of their operations is impossible, and as a result STAAR relies on its local managers and staff. Cultural factors and language differences can result in misunderstandings among internationally dispersed personnel. In early 2007, STAAR learned that the president of its German sales subsidiary, Domilens, had misappropriated corporate assets. While STAAR has implemented remedial efforts to reinforce its Code of Ethics and increase its oversight of Domilens, the risk that unauthorized conduct may go undetected will always be greater in foreign subsidiaries. Some countries may also have laws or cultural factors

that make it difficult to impose uniform standards and practices. For example, while STAAR's Code of Ethics requires all employees to certify they are not aware of code violations by others, German legal counsel has advised STAAR that in Germany it cannot legally compel ordinary employees (i.e., non-supervisors) to notify STAAR of breaches by others. STAAR believes the absence of such a requirement in its Code

Table of Contents

of Ethics for German employees is a risk inherent to doing business in Germany that may be mitigated, but not entirely eliminated, by other controls.

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 sales 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.

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 rights to the partners that could be exercised in the event of a change in control of STAAR.

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

Table of Contents

venture at book value. The terms of the principal agreements governing the joint venture are described in this Annual Report on Form 10-K under the heading *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 significantly 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 our 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.

Table of Contents

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

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

We spent 12.6% of our sales on research and development during the year ended December 29, 2006, and we expect to spend approximately 10% for this purpose 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.

Changes in reimbursement for our products by third-party payors could reduce sales of our products or make them less profitable.

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 in the U.S. and Europe. Third party payors in both government and the private sector continue to seek to manage costs by restricting the types of procedures they reimburse to those viewed as most cost-effective and by capping or reducing reimbursement rates. Whether they limit reimbursement prices for our products and or limit the surgical fees for a procedure that uses our products, these policies can reduce the sales volume of our reimbursed products, their selling prices or both.

In some countries government agencies control costs by limiting the number of surgical procedures they will reimburse. For example, a recent reduction in the number of authorized cataract procedures in Germany has affected the sales of our German subsidiary, Domilens. Similar changes could occur in our other markets.

The U.S. Congress has considered legislative proposals that would significantly change the system of public and private health care reimbursement, and will likely consider such changes again in the future. We are not able to predict whether new legislation or changes in regulations will take effect at the state or federal level, but if enacted these changes could have a significant effect on our business.

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

STAAR is regulated by regional, national, state and local agencies, including the Food and Drug Administration, the Department of Justice, the Federal Trade Commission, the Office of the Inspector General of the U.S. Department of Health and Human Services and other regulatory bodies, as well as governmental authorities in those foreign countries in which we manufacture or distribute products. The Federal Food, Drug, and Cosmetic Act, the Public Health Service Act and other federal and state statutes and regulations govern the research, development, manufacturing and commercial activities relating to medical devices, including their pre-clinical and clinical testing, approval, production, labeling, sale, distribution, import, export, post-market surveillance, advertising, dissemination of information and promotion. 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.

Table of Contents

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.

Regulatory investigations and allegations, whether or not they lead to enforcement action, can materially harm our business and its reputation.

Failure to comply with the requirements of the FDA or other regulators can result in civil and criminal fines, the recall of products, the total or partial suspension of manufacture or distribution, seizure of products, injunctions, whistleblower lawsuits, failure to obtain approval of pending product applications, withdrawal of existing product approvals, exclusion from participation in government healthcare programs and other sanctions. Any threatened or actual government enforcement action can also generate adverse publicity and require us to divert substantial resources from more productive uses in our business. Enforcement actions could affect our ability to commercially distribute our products and could materially harm our business

From time to time STAAR is subject to formal and informal inquiries by regulatory agencies, which may or may not lead to investigations or enforcement actions. Even when an inquiry results in no evidence of wrongdoing or is inconclusive, the agency generally is not required to notify STAAR of its findings and may not inform STAAR that the inquiry has been terminated.

STAAR maintains a hotline for employees to anonymously report any violation of laws, regulations or company policies, and investigates any allegation of improper conduct. Nevertheless, present or former employees may elect to bring complaints to regulators and enforcement agencies. The relevant agency will generally be obligated to investigate such complaints to assess their validity and obtain evidence of any violation that may have occurred. Even without a finding of misconduct, negative publicity about investigations or allegations of misconduct could harm our reputation with customers and the market for our common stock.

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

Table of Contents

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 in the U.S. 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.

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

- 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 \$6.31 to \$9.53 during the year ended December 29, 2006. 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.

Table of Contents**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 2007.

Item 3. *Legal Proceedings*

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 29, 2006.

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

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

Period	High	Low
2006		
Fourth Quarter	\$ 8.640	\$ 6.400
Third Quarter	7.800	6.310
Second Quarter	9.500	7.210
First Quarter	9.530	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

On March 23, 2007, the closing price of the Company's Common Stock was \$5.79. Stockholders are urged to obtain current market quotations for the Common Stock.

As of March 23, 2007, there were approximately 558 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 23, 2007, options to purchase 2,569,248 shares of Common Stock were exercisable.

Table of Contents**Stock Performance Graph**

The following graph compares the yearly and cumulative return on an investment in STAAR's common stock over the last five fiscal years to the yearly and cumulative return of the following over the same time period: (1) the composite of all United States and foreign companies listed on the Nasdaq Stock Market (the Nasdaq Index); and (2) the composite of all United States and foreign companies listed on the Nasdaq Stock Market that operate in the surgical, medical and dental instrument and supply industries (the Peer Index), based on Standard Industrial Classification (SIC) codes in the range of 3840 through 3849. The Company's SIC code is 3845. The comparison assumes \$100 was invested on December 28, 2001 in STAAR's common stock and in each of those indices, and that dividends were reinvested. The Center for Research in Security Prices of the University of Chicago's Graduate School of Business compiled the Peer Index and produced the graph. The stock price performance on the following graph is not necessarily indicative of future stock price performance.

In any of our filings under the Securities Act or Exchange Act that incorporate this Proxy Statement by reference, this graph will be considered excluded from the incorporation by reference and it will not be deemed a part of any such other filing unless we expressly state that the graph is so incorporated.

Comparison of Five-Year Cumulative Total Returns

CRSP Total Returns Index for:	12/2001	01/2003	01/2004	12/2004	12/2005	12/2006
STAAR SURGICAL CO	100.0	111.1	294.2	165.9	209.0	185.4
Nasdaq Stock Market (US & Foreign)	100.0	70.1	102.1	110.8	113.4	125.0
NASDAQ Stocks (SIC 3840 - 3849 US + Foreign) Surgical, Medical, and Dental Instruments and Supplies	100.0	81.3	119.2	139.4	153.0	161.4

Notes:

- A. The lines represent monthly index levels derived from compounded daily returns that include all dividends.
- B. The indexes are reweighted daily, using the market capitalization on the previous trading day.
- C. If the monthly interval, based on the fiscal year-end, is not a trading day, the preceding trading day is used.
- D. The index level for all series was set to \$100.0 on 12/28/2001.

Table of Contents**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 29, 2006, December 30, 2005, December 31, 2004, January 2, 2004 and January 3, 2003. 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 29, 2006 and December 30, 2005, 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 2, 2004, and January 3, 2003, and the consolidated balance sheet data set forth below at December 31, 2004, January 2, 2004, and January 3, 2003 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				
	December 29, 2006	December 30, 2005	December 31, 2004	January 2, 2004	January 3, 2003
(In thousands except per share data)					
Statement of Operations					
Sales	\$ 56,282	\$ 51,303	\$ 51,685	\$ 50,409	\$ 47,880
Royalty and other income				49	368
Total revenues	56,282	51,303	51,685	50,458	48,248
Cost of sales	29,849	27,517	25,542	22,621	24,099
Gross profit	26,433	23,786	26,143	27,837	24,149
Selling, general and administrative expenses					
General and administrative	10,891	9,727	9,253	9,343	8,959
Marketing and selling	22,395	18,552	20,302	19,509	16,833
Research and development	7,080	5,573	6,246	5,120	4,016
Notes receivable reserves (reversals)/other charges	(331)	746	500	390	1,454
Total selling, general and administrative expenses	40,035	34,598	36,301	34,362	31,262
Operating loss	(13,602)	(10,812)	(10,158)	(6,525)	(7,113)
Total other income (expense), net	95	854	(88)	(637)	(785)
Loss before income taxes and minority interest	(13,507)	(9,958)	(10,246)	(7,162)	(7,898)

Edgar Filing: STAAR SURGICAL CO - Form 10-K

Income tax provision	1,537	1,239	1,057	1,127	8,805
Minority interest		(22)	29	68	75
Net loss	\$ (15,044)	\$ (11,175)	\$ (11,332)	\$ (8,357)	\$ (16,778)
Basic and diluted net loss per share	\$ (0.60)	\$ (0.47)	\$ (0.58)	\$ (0.47)	\$ (0.98)
Weighted average number of basic and diluted shares	25,227	23,704	19,602	17,704	17,142
Balance Sheet Data					
Working capital	\$ 14,363	\$ 22,735	\$ 19,103	\$ 15,883	\$ 7,095
Total assets	47,770	52,755	51,973	47,376	45,220
Notes payable and current portion of long-term debt	1,802	1,676	3,004	2,950	5,845
Stockholders' equity	31,760	40,366	37,840	35,219	30,551

Table of Contents

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, 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:

building the U.S. market for the ICL 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.

Building the U.S. market for the ICL and securing U.S. approval of the TICL. Because the ICL's design has advantages over other refractive procedures for many patients and its proprietary nature permits STAAR to maintain its profit margin, STAAR's management believes that increased sales of the ICL are the key to the company's return to profitability. U.S. market penetration is considered essential because of the size of the U.S. refractive surgery market and the perceived leadership of the U.S. in adopting innovative medical technologies.

STAAR's strategy for the U.S. market is to educate eye care professionals on the high quality of visual outcomes of the ICL for a significant portion of patients seeking refractive surgery, and to make 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.

To develop specialized resources to meet the challenge of penetrating the refractive market, and to take advantage of opportunities to improve cataract product sales, STAAR split its Sales and Marketing Department into two separate groups in the first quarter of 2007. Among other advantages, the split will enable the Sales Department to focus on the development of STAAR's direct sales model in regions where STAAR will sell directly, and to better coordinate sales initiatives with the independent Regional Marketing Representatives in those regions where STAAR will continue to rely on independent representatives.

Table of Contents

STAAR has relied on a largely independent sales force to sell its cataract products, and over the last several months has worked to re-orient this sales force to deal with the very different practice environment for refractive products. While STAAR expects to continue to rely on its independent sales force in some regions, it has moved to a direct sales structure in other regions. Because the refractive surgery market has been dominated by corneal laser-based techniques, STAAR faces special challenges in introducing an intraocular refractive implant. STAAR has developed a number of marketing tools and practice support programs to increase the use of the ICL and awareness of its advantages at laser-oriented surgery centers.

The Visian ICL was approved by the FDA for treatment of myopia on December 22, 2005. The U.S. rollout of the product began in the first quarter of 2006. As of December 29, 2006, 306 surgeons had completed training and 350 had completed training by March 26, 2007. STAAR recognized \$4,172,000 of U.S. sales revenue from ICLs in 2006. It is too early to determine whether STAAR's strategy will be successful or to estimate the ultimate size of the U.S. market for ICLs.

STAAR believes that the Visian 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. 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. Securing FDA approval of the TICL is therefore an integral part of STAAR's strategy to develop its U.S. refractive market. STAAR submitted a Pre-Market Approval (PMA) application for the TICL to the FDA on April 28, 2006, and received comments from the Office of Device Evaluation (ODE) on November 20, 2006 requesting that STAAR submit an amended application. In subsequent discussion the ODE indicated that it expects to submit the amended application to review by the FDA Ophthalmic Devices Panel. As of the date of this Report, STAAR is preparing an amendment to the TICL application addressing the ODE comments.

Generating further growth of the ICL and TICL in international markets. The ICL and TICL are sold in more than 40 countries. International sales of refractive implants have continued a steady rate of growth, increasing approximately 50% in 2006 over the preceding year. STAAR believes that the international market for its refractive products has the potential for further growth, both through the introduction of the ICL and TICL in new territories and expanded market share in existing territories. In recent periods STAAR has received the majority of its revenue from international markets, and sales of ICLs have represented an increasing share of that revenue. STAAR received approval for the ICL in China on July 31, 2006 and we are awaiting approval of the TICL there as well. We also continue to seek new approvals for the ICL and TICL in other countries, but these approvals are at the discretion of the local authorities.

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. During the last several years STAAR has experienced a decline in U.S. sales of IOLs. STAAR's management believes the decline principally resulted from the slow pace of cataract product improvement and enhancement during a period when we had to devote most of our research and development resources to introducing the ICL and to resolving the regulatory and compliance issues raised by the FDA, and the harm to our reputation from warning letters and other correspondence with the FDA during 2004 and 2005.

STAAR seeks to reverse the decline in its domestic cataract market share by the introduction of enhanced design IOLs and improved delivery systems in 2007 and 2008. The completion in 2005 of initiatives to revamp STAAR's systems of regulatory compliance and quality management permitted STAAR to shift resources back to product development. In particular, STAAR has focused on the following projects intended to expand and improve our cataract product offering:

A Collamer Toric IOL;

New Collamer IOL models featuring an aspheric optic design, in a three-piece configuration;

New silicone IOL models featuring aspheric optics and a squared edge configuration;

Enhancements to the injector system for our three-piece Collamer IOL to improve delivery;

An all new injector system for the three-piece Collamer IOL;

Table of Contents

A micro-incision injector for the one-piece Collamer IOL; and

Development of a preloaded injector system for our new silicone aspheric IOLs.

STAAR cautions that the successful development and introduction of new products is subject to risks and uncertainties, including the risk of unexpected delays.

STAAR also believes that expanding the U.S. market for the ICL should also improve the selling environment for STAAR's cataract products, especially cataract lenses made of the same biocompatible Collamer material used in the ICL. STAAR intends that the split of its Sales and Marketing Department will help it take advantage of the opportunities presented by the introduction of new cataract products and the improved selling environment for STAAR's products created by the ICL.

On January 22, 2007, the Centers for Medicare and Medicaid Services (CMS) issued a ruling that allows cataract patients receiving reimbursement by Medicare to choose a lens that also corrects astigmatism. Under the ruling, patients may elect to pay a premium for the correction of pre-existing astigmatism, while Medicare provides the customary reimbursement for cataract surgery. STAAR expects its silicone Toric IOL, currently one of two IOLs approved for sale in the U.S. for treatment of cataracts and astigmatism, to be covered by the CMS ruling. STAAR believes that the CMS ruling will increase the profitability of its sales of Toric IOLs and generate greater interest in implanting the product. In addition, STAAR expects to introduce a Toric IOL made of its proprietary Collamer material, which would also likely fall under the CMS ruling and compete with our competitor's acrylic model. STAAR cannot estimate the increased revenue that may result from the CMS ruling at this time.

While STAAR's U.S. cataract product sales, which include accessory products such as surgery packs and phacoemulsification equipment, declined 5% during 2006, U.S. cataract product sales for the fourth quarter of 2006 increased 6% compared with the same period in 2005. Despite the decline in total U.S. cataract sales for the full year, the fourth quarter sales in 2006 is a marked improvement compared with the first three quarters of 2006, which have improved from 13% down in the first quarter of 2006 when compared to their respective periods in 2005.

To reverse the decline in U.S. IOL sales, STAAR must overcome several short and long-term challenges, including overcoming reputational harm from the FDA's past findings of compliance deficiencies, successfully completing planned development projects, and organizing and managing a combined direct and independent sales force. 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 regulated by the FDA. We also must satisfy the requirements of the International Standards Organization (ISO) to maintain approval to sell products in the European Community and other regions. Failure to demonstrate substantial 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.

The FDA's most recent general quality inspections of STAAR's facilities were a post-market inspection of the Monrovia, California and Aliso Viejo, California facilities between August 2, 2006 and August 7, 2006, and a

post-market inspection of the Nidau, Switzerland facilities between September 26 and September 28, 2006. These inspections resulted in no observations of noncompliance. Based in part on these inspections and the FDA inspections conducted in 2005, STAAR believes that it is substantially in compliance with the FDA's Quality System Regulations and Medical Device Reporting regulations. Nevertheless, the FDA's past findings of compliance deficiencies have harmed our reputation in the ophthalmic industry and affected our product sales.

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

Table of Contents

management expects its strategy to include devoting significant resources and attention to strict regulatory compliance and continuous improvement in quality.

In keeping with its compliance strategy, STAAR hired Rob Lally to serve as Vice President, Quality Assurance and Regulatory affairs on October 23, 2006. Prior to joining STAAR, Mr. Lally was most recently the Director of International Regulatory Affairs at Johnson & Johnson Vision Care in Florida. Mr. Lally previously served as Head of the Medical Devices Sector of the British Standards Institution, the National Standards Body of the United Kingdom responsible for independent certification of a variety of systems and products. Prior to this, he was a senior consultant at Quintiles, a global quality and regulatory consulting firm. Mr. Lally also served as General Manager, Quality and Certification at AMTAC Laboratories, a leading European Union notified body where he managed the medical device and drug sector.

On March 14, 2007, the Bioresearch Monitoring Program of the FDA Office of Regulatory Affairs (BIMO) concluded a routine audit of the Company's clinical trial records as a sponsor of biomedical research in connection with the Company's Supplemental Pre-Market Approval application for the TICL. At the conclusion of the audit the Company received eight Inspectional Observations on FDA Form 483 noting noncompliance with regulations. The Company is preparing its response to the Inspectional Observations and expects to address the concerns raised by BIMO through voluntary corrective actions. Most of the observed instances of non-compliance took place during the 2000-2004 period and the Company expects to show that some of these have already been addressed by corrective actions made in response to BIMO's observations of December 11, 2003 in connection with the Company's application for the ICL. The Company does not believe that the Inspectional Observations affect the integrity of the Toric clinical study. However, the determination of whether the Inspectional Observations affect the use of the Toric clinical study in STAAR's pending Toric application will be at the discretion of the ODE. Obtaining FDA approval of medical devices is never certain.

Financing Strategy

While STAAR's international business generates positive cash flow and 60% of STAAR's revenue, STAAR has reported losses on a consolidated basis over the last several 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, exercise of options, the repayment of directors' notes and debt financing.

STAAR's management believes that in the near term its best prospect for returning its U.S. and consolidated operations to profitability is achieving significant U.S. sales of the ICL. 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 2007.

To provide additional sources of available working capital, STAAR entered into two debt financing arrangements in 2006 and 2007.

On March 21, 2007, STAAR entered into a loan arrangement with Broadwood Partners, L.P. (Broadwood). Pursuant to a Promissory Note (the Note) between STAAR and Broadwood, Broadwood loaned \$4 million to STAAR. The Note has a term of three years and bears interest at a rate of 10% per annum, payable quarterly. The Note is not secured by any collateral, may be pre-paid by STAAR at any time without penalty, and is not subject to covenants based on financial performance or financial condition (except for insolvency). As additional consideration for the loan STAAR also entered into a Warrant Agreement (the Warrant Agreement) with Broadwood granting the right to

purchase up to 70,000 shares of Common Stock at an exercise price of \$6, exercisable for a period of six years. The Note also provides that so long as a principal balance remains outstanding on the Note STAAR will grant additional warrants each quarter on the same terms as the Warrant Agreement. The warrant agreement provides that STAAR will register the stock for resale with the SEC. Based on publicly available information filed with the Securities and Exchange Commission (the SEC), on the date of the transaction Broadwood Partners L.P. beneficially owned 2,492,788 shares of the Company's common stock, comprising 9.7% of the Company's common stock as of March 21, 2007, and Neal Bradsher, President of Broadwood Partners, L.P.,

Table of Contents

may have been deemed to beneficially own 2,518,688 shares of the Company's common stock, comprising 9.8% of the Company's common stock as of that date.

On June 8, 2006 STAAR signed a Credit and Security agreement with Wells Fargo Bank for a revolving credit facility. The credit facility provides for borrowings of 85% of eligible accounts receivable with a maximum of \$3.0 million, carries an interest rate of prime plus 1.5%, and is secured by substantially all of the assets of STAAR's U.S. operations. The term of the agreement is three years and it contains certain financial covenants relating to minimum calculated net worth, net loss, liquidity and restrictions on Company investments or loans to affiliates and investments in capital expenditures, which only apply if the Company borrows and/or maintains an outstanding advance. No borrowings were outstanding as of December 29, 2006. However, as STAAR does not satisfy minimum financial covenants in its U.S. operations that are a condition to borrowing, no borrowings are available.

In addition, STAAR's Swiss subsidiary has \$653,000 in borrowing availability under its \$2.5 million line of credit for use in Swiss operations.

STAAR may seek additional debt or equity financing to provide working capital, finance new business initiatives, expand its business or make acquisitions. Because of our history of losses, our ability to obtain adequate financing on satisfactory terms is limited. STAAR's cash resources are discussed in further detail under the caption *Liquidity and Capital Resources* below.

Investigation of Fraud at Domilens GmbH

Domilens GmbH is a wholly owned indirect subsidiary of STAAR Surgical Company based in Hamburg, Germany. It distributes ophthalmic products made by both STAAR and other manufacturers. During fiscal year 2006 Domilens reported sales of \$21.1 million.

On January 18, 2007, Guenther Roepstorff, president of Domilens, notified STAAR he had admitted to the German Federal Ministry of Finance that without STAAR's knowledge he had diverted property of Domilens to a company under his control over a four-year period between 2001 and 2004. Mr. Roepstorff made this admission in connection with an audit conducted by the Ministry in 2006, which examined the financial records of Mr. Roepstorff, Domilens and the company to which he owned and diverted the property, Equimed GmbH (currently known as eyemaxx GmbH), covering the four-year period.

Immediately after learning these facts STAAR commenced an internal investigation of Domilens. On January 20, 2007, the Audit Committee of STAAR's Board of Directors engaged PricewaterhouseCoopers LLP (PwC) to conduct a forensic audit in connection with the investigation by legal counsel. The Committee subsequently engaged the law firm of Taylor Wessing, through its Hamburg office, as independent German legal counsel. The investigation included a comprehensive forensic review of the accounting records, documents and electronic records of Domilens and interviews of current employees and Mr. Roepstorff. On March 6, 2007, the Audit Committee of the Board of Directors of STAAR Surgical Company received PwC's final report.

Key findings. PwC investigated instances of misappropriation of corporate assets by Mr. Roepstorff between 2001 and 2006. Areas of fraudulent activity investigated by PwC included diversions of sales of IOLs and equipment to Equimed GmbH, payments to Mr. Roepstorff disguised as prepayments to suppliers and unauthorized borrowing. It is estimated that from 2001 through 2006 these activities diverted assets having a book value of approximately \$400,000 and resulted in unreported proceeds to Equimed and Mr. Roepstorff of approximately \$1,000,000.

PwC identified Mr. Roepstorff's ability to override the internal controls implemented by STAAR as a key factor in his ability to accomplish fraudulent transactions and avoid detection. In particular, they found that even after STAAR had

acquired full control of Domilens and implemented further oversight he continued to run the company as his own and had a dominant presence with employees. PwC found evidence that, notwithstanding the requirements of STAAR's Code of Ethics, some Domilens employees had been aware of improper activities by Mr. Roepstorff and in some instances cooperated in documenting the activities in a manner that aided concealment. However, there is no evidence that other employees received any portion of the diverted assets or other payment for cooperation.

Table of Contents

PwC also identified inadequate oversight of Domilens by STAAR AG and inadequate management oversight by STAAR as significant factors enabling Mr. Roepstorff to accomplish his actions. PwC has determined that a greater degree of scrutiny would have likely led to earlier detection of irregularities at Domilens.

Impact on financial statements. Domilens' financial results are consolidated into the audited financial statements of STAAR. STAAR has reviewed its historical financial statements, and has determined that properly accounting for past transactions in Domilens in light of the information provided by PwC's investigation did not result in a material change in STAAR's reported results of operations or reported financial condition for historical periods.

STAAR has determined that the events at Domilens revealed a material weakness in its internal controls over financial reporting. See *Item 9A. Controls and Procedures* Management Report on Internal Control Over Financial Reporting.

Expenses related to Domilens irregularities. It is currently estimated that the fees and reimbursable expenses of advisors incurred by STAAR in connection with the investigation will total approximately \$750,000, which will be recorded in fiscal year 2007. In addition, STAAR has reserved approximately \$700,000 against additional taxes that may be assessed for unreported sales, but will seek to reduce that amount in discussions with the German Ministry of Finance. The estimated tax liability was recorded in the fourth quarter of fiscal year 2006.

Other Actions. STAAR suspended all of Mr. Roepstorff's duties as president on January 19, 2007. He voluntarily resigned from his employment with Domilens on January 23, 2007. STAAR will provide all of Domilens' employees further training in their duties as employees and in STAAR's Code of Ethics. In addition, based on the advice of German counsel, the degree of individual culpability and other factors, STAAR may take other disciplinary actions, including possible termination of employees or monitoring of selected employees during a probationary period.

Other Recent Highlights

Growth in International Sales of Visian ICLs and Preloaded Silicone IOLs. The decline in the U.S. cataract business during 2006 was offset in part by a 50% increase in international sales of the ICL and TICL. In addition, the preloaded silicone IOL injector system developed with our joint venture partner Canon Staar experienced strong sales in international markets, growing 21% for the year. This growth in the business contributed to an increase in international sales of 4% for fiscal 2006 compared with 2005.

Job Actions by Doctors in Germany. STAAR receives significant revenue from its German subsidiary, Domilens GmbH, a distributor of ophthalmic products manufactured by STAAR and other manufacturers. As is the case in most countries, purchases of Domilens' cataract-related products in Germany depend on government reimbursement of cataract surgery. Germany has recently made a number of cost-cutting changes in its medical reimbursement policies, including a requirement that government-employed surgeons reduce the number of cataract surgeries performed to 20% below 2004 rates. In response to these changes in reimbursement policies, many medical doctors throughout Germany initiated job actions during the first and second quarters of 2006 such as strikes or slow-downs in which doctors provided only the most essential services to patients. While doctors and state-run and university clinics reached a settlement in June, strikes continue at city-run hospitals throughout Germany during the third quarter, but were ultimately resolved. These job actions, and the mandatory reduction in the number of cataract procedures, caused a significant reduction in ophthalmic surgeries and reduced sales of distributed products by Domilens, which during 2006 declined 6% compared to 2005, significantly impacting international and global sales of cataract product for the year. However, fourth quarter sales in Germany of 2006 improved over the fourth quarter of 2005 by 5% indicating we may have seen the worst in this market.

Competition with Multifocal IOLs. The U.S. IOL market continues to be affected by sales of multifocal and accommodating lenses resulting from a ruling of the Centers for Medicare and Medicaid Services (CMS). The ruling permits Medicare-covered cataract patients to receive more highly priced multifocal or accommodating IOLs (sometimes referred to as presbyopic lenses) 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 increased the number of patients to whom surgeons offer the alternative of the higher-priced lenses. While STAAR s

Table of Contents

U.S. cataract product sales increased in the first, second, and fourth quarters of 2006 over the preceding quarter, remained flat in the third quarter of 2006 compared to the same period in 2005, sales volume might have been greater were it not for increased sales of multifocal and accommodative lenses.

In January 2007, the CMS made a similar ruling, that allows a Medicare patient to pay a premium for a lens that also corrects astigmatism. STAAR expects this ruling will result in increased sales revenue from its silicone Toric IOLs, currently one of only two lenses of this type in the U.S. market, and will enhance the market for a Collamer Toric IOL currently in development. Nevertheless, with the help of the CMS ruling, presbyopic lenses are expected to claim a share of the cataract market in the future, and STAAR does not offer a lens of this type.

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 2006, sales from international operations represented 60% 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 2006, 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 increased to 47.0% for fiscal year 2006, compared with 46.4% in 2005. The improvement in gross profit from 2005 generally resulted from increased volume of higher margin ICLs in the U.S., partially offset by an obsolescence charge \$807,000 against certain IOL inventory in anticipation of new product launches in 2007 and higher IOL and ICL unit costs due to lower manufacturing volumes.

Research and Development. We spent approximately 13% of our sales on research and development (which includes regulatory and quality assurance expenses) during fiscal 2006, and we expect to spend approximately 10% of our sales on an annual basis in the future.

Cash Flow. We exited the year with approximately \$7.9 million in cash, cash equivalents and restricted short-term investments compared with \$12.7 million at December 30, 2005. We used approximately \$8.6 million for operating activities during fiscal 2006, which is 24% above the \$7.0 million used during fiscal 2005. However, cash used in operating activities in 2006, which was at its highest level for the year in the first quarter of 2006 when the ICL was first introduced in the U.S. market, declined in each of the three subsequent quarters. Purchases of property and equipment were approximately \$779,000. During the year we received approximately \$2.9 million in proceeds from stock options and \$1.2 million in payments on notes from a former director. As a result of these proceeds, the net cash usage (see *Liquidity and Capital Resources – Non-GAAP Measures*) for fiscal 2006 was \$4.8 million, a 52% improvement over the \$10.0 million reported for fiscal 2005. During 2006 we obtained additional sources of financing such as the \$3.0 million Wells Fargo LOC and \$1.8 million in lease financing and we expect to continue to identify alternative sources of liquidity to support operations. The Company expects to reduce and ultimately reverse its operating losses and negative cash flows as ICL sales reach targeted levels and the TICL is approved in the U.S. In addition, we will continue to pursue cost savings opportunities, wherever possible, to conserve cash.

Table of Contents**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 Sales			Percentage Change	
	December 29, 2006	December 30, 2005	December 31, 2004	2006 vs. 2005	2005 vs. 2004
Net Sales	100.0%	100.0%	100.0%	9.7%	(0.7)%
Cost of sales	53.0%	53.6%	49.4%	8.5%	7.7%
Gross profit	47.0%	46.4%	50.6%	11.1%	(9.0)%
General and administrative	19.4%	19.0%	17.9%	12.0%	5.1%
Marketing and selling	39.8%	36.2%	39.3%	20.7%	(8.6)%
Research and development	12.6%	10.9%	12.1%	27.1%	(10.8)%
Note Reserve (reversals)	(0.6)%	1.4%	1.0%		49.3%
Operating loss	(24.2)%	(21.1)%	(19.7)%	25.8%	6.4%
Total other income (expense), net	0.2%	1.7%	(0.1)%	(88.9)%	
Loss before income taxes and minority interest	(24.0)%	(19.4)%	(19.8)%	35.6%	(2.8)%
Provision for income taxes	2.7%	2.4%	2.0%	24.4%	17.4%
Minority interest			0.1%		
Net loss	(26.7)%	(21.8)%	(21.9)%	34.6%	(1.4)%

2006 Fiscal Year Compared to 2005 Fiscal Year**Net sales**

Net sales for the year ended December 29, 2006 (fiscal 2006) were \$56,282,000, an increase of 9.7% compared with net sales for the year ended December 30, 2005 (fiscal 2005) of \$51,303,000. Changes in currency exchange rates did not have a material impact on net sales for fiscal 2006.

U.S. net sales for fiscal 2006 increased 19.1% to \$22,293,000 compared with fiscal 2005. The increase in U.S. sales reflects both the recent approval of the Visian ICL for the treatment of myopia, and were partially offset by a 5% decrease in U.S. cataract product sales. The Company has lost increasing market share in the U.S. over the last several years as it has not kept pace with the competition in introducing new and enhanced cataracts products due to the Company's focus on bringing the Visian ICL to the U.S. market. U.S. sales of the Visian ICL, which was launched in the U.S. in February 2006, were \$4,172,000 for fiscal 2006. The Company expects to grow ICL sales and reverse declining cataract sales trends and regain market share as it continues the process of training ICL surgeons and

introduces enhanced cataract products to the market in 2007 and beyond.

International net sales for fiscal were \$33,990,000, an increase of 4% compared with fiscal 2005 and were impacted by a 50% increase in refractive product sales but partially offset by a decline of 5% in cataract product sales. The decline in international cataract sales is primarily due to the impact in 2006 of doctor strikes in Germany, one of STAAR's largest cataract sales markets. The labor disputes were settled in 2006 and the Company believes the declining cataract sales trends in Germany will reverse in 2007.

During fiscal 2006, global sales of ICLs and TICLs grew 129% to \$12,093,000 compared with \$5,287,000 in fiscal 2005. Total refractive sales during fiscal 2006 grew 134% to \$12,514,000 compared with \$5,347,000 in fiscal 2005 due to the launch of the ICL in the U.S. and increased international ICL sales in 2006.

The Company expects continued growth in sales, both in the U.S. and internationally, as the ICL and TICL gain broader acceptance and new cataract products are introduced.

Table of Contents

Gross profit margin

Gross profit margin for the full year 2006 was 47.0% compared with 46.4% for 2005. Gross profit for 2006 was impacted by obsolescence charges of \$807,000 for certain IOL inventory in anticipation of new product launches in 2007 and to a lesser degree slower moving diopters of other lenses. Management intends to mitigate the risk of write-off of this and other product but felt it prudent to take this action as cannibalization of existing product is likely as new products roll out. This charge reduced gross profit margin by approximately 1.4%. Excluding this charge, 2006 gross profit margin would have increased to 48.4%, a 2.0 percentage point improvement compared with 2005.

Standard margin, which represents the margin associated with the direct costs of production and excludes other cost of sales, for 2006 was 53.9%, an increase of 1.2% compared with 2005. IOL margins for the year decreased 5% to 50%, due to an overall 2% decrease in average selling prices, a 2% decrease in IOL unit volume, and a 9% increase in average unit costs. ICL margins increased 2% to 82% due to the launch of the product in the U.S. where the Company realized margins of approximately 89%. International ICL/TICL margins at 79% were down 1% from the previous year due to higher costs. Margins on all other products decreased 2% due to higher costs. For 2006, other cost of sales was \$3.9 million, an increase of \$633,000 compared with 2005. The increase in other cost of sales is due to the aforementioned inventory reserves and increased royalties, partially offset by a decrease in freight and other costs.

The Company expects gross profit margin to increase as sales of ICLs become a larger percentage of overall revenue, U.S. cataract sales continue to grow and as enhanced cataract products are delivered to the market.

General and administrative

General and administrative expenses for fiscal 2006 increased 12% or \$1,165,000 over fiscal 2005. Excluding the \$952,000 impact of FAS 123R for fiscal 2006, general and administrative expenses increased 2% in fiscal 2006 over fiscal 2005 as a result of general cost increases. The Company does not expect significant increases in general and administrative expenses in 2007.

Marketing and selling

Marketing and selling expenses for fiscal 2006 increased 21% or \$3,842,000 compared with fiscal 2005. Excluding the \$419,000 impact of FAS 123R for fiscal 2006, marketing and selling expenses increased 19% in fiscal 2006. The increase in marketing and selling expenses for fiscal 2006 primarily resulted from increased costs to support the roll-out of the Company's refractive products in new territories, including the U.S., and increased commissions. The Company expects sales and marketing expense to decrease slightly as a percentage of sales over 2006 but increase in dollars due to increased commissions in the U.S. on higher sales.

Research and development

Research and development expenses, including regulatory and clinical expenses, for fiscal 2006 increased 27% or \$1,507,000 compared with fiscal 2005. Excluding the impact of the implementation of FAS 123R, which was \$262,000 for fiscal 2006, research and development expenses increased 22%. The increase in research and development expenses, excluding the impact of the adoption of FAS 123R, is due to costs associated with new product development and TICL regulatory and FDA submission costs. The Company expects to spend approximately 10% of revenues in 2007 on its research and development activities.

Note reserves (reversals)

During 2006, the Company settled the last of its notes receivable from former directors and officers totaling \$1,961,000 (including accrued interest) for a cash payment of \$175,000 and proceeds from the sale of 120,000 shares of pledged Company stock of \$870,000. The deficiency on the notes was applied against reserves recorded against the notes in 2005 and 2004 and \$331,000 of excess reserves was reversed during fiscal 2006.

Table of Contents

Other income (expense), net

Other income, net for fiscal 2006 was \$95,000, compared to fiscal 2005 when it was \$854,000. The principal reasons for the decrease in other income are due to 1) \$65,000 of exchange losses recorded during the year versus \$334,000 of exchange gains recorded during fiscal 2005; 2) decreased interest income due to decreased cash balances; 3) increased interest expense due to lease financing obtained in 2006; and 4) a decrease in earnings from the Company's joint venture and other miscellaneous income decreases.

Income taxes

The Company recorded income taxes of \$1.5 million for fiscal 2006 and \$1.2 million for fiscal 2005, based on the income of the Company's German subsidiary including taxes of approximately \$700,000 that were accrued based on the results of a tax audit of the German subsidiary by the German tax authorities, see *Overview - Investigation of Fraud at Domilens GmbH*.

2005 Fiscal Year Compared to 2004 Fiscal Year

Revenues

Net sales for the years ended 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 Visia[®] 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.

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.

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.

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.

Table of Contents

Note reserves (reversals)

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.

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.

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 29, 2006 and December 30, 2005, the Company had \$7.9 million and \$12.7 million, respectively, of cash, cash equivalents and restricted short-term investments.

Net cash used in operating activities was \$8.6 million, \$7.0 million, and \$8.8 million for fiscal 2006, 2005, and 2004, respectively. For fiscal 2006, cash used in operations was the result of increased net losses, adjusted for depreciation, amortization, expense related to the implementation of FAS 123R, and other miscellaneous non-cash items, and further offset by increases in working capital. 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.

Accounts receivable was \$6.5 million in 2006, \$5.1 million in 2005, and \$6.2 million in 2004. The increase in accounts receivable is due to increased sales in the U.S. during fiscal 2006 and in international markets. Days Sales Outstanding (DSO) decreased slightly from 41 days in 2004 to 38 days in 2005, and increased to 39 days in 2006. The

Company expects DSO to improve in 2007 assuming increased sales of the ICL in the U.S. which generally have shorter payment terms than U.S. cataract sales or all other products sold internationally.

Inventories at the end of fiscal 2006, 2005, and 2004 was \$13.0 million, \$14.7 million, and \$15.1 million, respectively. Day s inventory on hand decreased from 186 days in 2004 and 235 days in 2005 to 162 days in 2006.

Net cash provided by (used in) investing activities was approximately \$145,000, \$4,077,000, and (\$7,294,000), for fiscal 2006, 2005, and 2004, respectively. The decrease from 2005 to 2006 is due primarily to changes related to the purchase and sale of short term investments as the Company no longer holds the

Table of Contents

investments. During 2006, the Company's principal investments were in property and equipment. Investments in property and equipment were \$779,000, \$1.2 million, and \$1.7 million for fiscal 2006, 2005, and 2004, respectively. The investments are generally made to upgrade and improve existing production equipment and processes. Investments in property and equipment for 2006 were more than offset by proceeds of approximately \$1.2 million from the settlement of notes receivable of a former director.

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 sales 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.

Net cash provided by financing activities was approximately \$2,809,000, \$12,298,000, and \$12,547,000 for fiscal 2006, 2005, and 2004, respectively. Cash provided by financing activities in 2006 resulted from the receipt of \$2.9 million of proceeds from stock option exercises. 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.

Credit Facilities

The Company and its subsidiaries have credit facilities with different lenders to support operations in the U.S., Switzerland and Germany, respectively.

On June 8, 2006 the Company signed a Credit and Security agreement with Wells Fargo Bank for a revolving credit facility. The credit facility provides for borrowings of 85% of eligible accounts receivable with a maximum of \$3.0 million, carries an interest rate of prime plus 1.5%, and is secured by substantially all of the assets of the Company's U.S. operations. The term of the agreement is three years and it contains certain financial covenants relating to minimum calculated net worth, net loss, liquidity and restrictions on Company investments or loans to affiliates and investments in capital expenditures, which only apply if the Company borrows and/or maintains an outstanding advance. No borrowings were outstanding as of December 29, 2006. As the Company does not satisfy minimum financial covenants in its U.S. operations that are a condition to borrowing, no borrowings are available. The Company intends to seek to renegotiate the conditions to borrowing under the agreement based on its most recent financial projections.

On March 21, 2007, STAAR entered into a loan arrangement with Broadwood Partners, L.P. ("Broadwood"). Pursuant to a Promissory Note (the "Note") between STAAR and Broadwood, Broadwood loaned \$4 million to STAAR. The Note has a term of three years and bears interest at a rate of 10% per annum, payable quarterly. The Note is not secured by any collateral, may be pre-paid by STAAR at any time without penalty, and is not subject to covenants based on financial performance or financial condition (except for insolvency). Based on publicly available information filed with the Securities and Exchange Commission (the "SEC"), on the date of the transaction Broadwood Partners L.P. beneficially owned 2,492,788 shares of the Company's common stock, comprising 9.7% of the Company's common

stock as of March 21, 2007, and Neal Bradsher, President of Broadwood Partners, L.P., may have been deemed to beneficially own 2,518,688 shares of the Company's common stock, comprising 9.8% of the Company's common stock as of that date.

The Company's lease agreement with Farnam Street Financial, Inc., as amended on October 9, 2006, provides for purchases of up to \$1,500,000 of property, plant and equipment. In accordance with the requirements of SFAS 13

Table of Contents

Accounting for Leases, purchases under this facility are accounted for as capital leases and have a three-year term. Under the agreement, the Company has the option to purchase any item of the leased property, at the end of the respective items lease terms, at a mutually agreed fair value. Approximately \$573,000 in borrowings were available under this facility as of December 29, 2006.

The Company's lease agreement with Mazuma Capital Corporation, as amended on August 16, 2006, provides for purchases of up to \$301,000 of property, plant and equipment. In accordance with the requirements of SFAS 13

Accounting for Leases, purchases under this facility are accounted for as capital leases and have a two-year term. The Company is required to open a certificate of deposit as collateral in STAAR Surgical Company's name at the underwriting bank for 50% of the assets funded by Mazuma. As of December 29, 2006, the Company had a certificate of deposit for approximately \$150,000 recorded as short-term investment restricted with a 12-month term at a fixed interest rate of 4.5%. The agreement also provides that the Company may elect to purchase any item of the leased property at the end of its lease term for \$1. No borrowings were available under this facility as of December 29, 2006.

The Company's Swiss credit agreement, as amended on August 2, 2004, provides for borrowings of up to 3.0 million Swiss Francs CHF (approximately \$2.4 million based on the rate of exchange on December 29, 2006) for use in the Company's Swiss operations, permits either fixed-term or current advances, and does not have a termination date. The interest rate on current advances is 6.25% and 6.0% per annum, respectively, at December 29, 2006 and December 30, 2005, plus a commission rate of 0.25% payable quarterly. There were no current advances outstanding at December 29, 2006. The base interest rate for fixed-term advances follows Euromarket conditions for loans of a corresponding term and currency plus an individual margin (5.0% at December 29, 2006 and 4.25% at December 30, 2005, respectively). Fixed-term borrowings outstanding under the note at December 29, 2006 and December 30, 2005, respectively, were CHF 2.2 million (approximately \$1.8 million based on the rate of exchange at December 29, 2006) and CHF 2.2 million (approximately \$1.7 million based on the rate of exchange on December 30, 2005). 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 German subsidiary entered into a credit agreement on August 30, 2005. The renewed credit agreement provides for borrowings of up to 100,000 EUR (\$131,000 at the rate of exchange on December 29, 2006), at a rate of 8.5% per annum and does not have a termination date. The credit facility is not secured. There were no borrowings outstanding as of December 29, 2006 and December 30, 2005.

The Company was in compliance with the covenants of its foreign credit facilities as of December 29, 2006.

The following table represents the Company's known contractual obligations as of December 29, 2006 (in thousands):

Contractual Obligations	Total	Payments Due by Period			More Than 5 Years
		Less Than 1 Year	1-3 Years	3-5 Years	
Notes payable	\$ 1,802	\$ 1,802	\$	\$	\$
Capital lease obligations	1,720	647	1,073		
Operating lease obligations	4,254	1,344	2,637	273	
Purchase obligations	1,289	600	689		

Edgar Filing: STAAR SURGICAL CO - Form 10-K

Other current-term liabilities	927	927			
Open purchase orders	1,278	1,278			
Total	\$ 11,270	\$ 6,598	\$ 4,399	\$ 273	\$

The table presented above excludes employment agreements for two employees of our Australian subsidiary.

Table of Contents

On March 23, 2007 the Company executed a \$4.0 million note with Broadwood Partners, LP. The obligation has been excluded from the table because it was not outstanding at December 29, 2006.

While the Company's international business generates positive cash flow and represents approximately 60% of consolidated net sales, the Company has reported losses on a consolidated basis for several 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 these years the Company has secured additional capital to sustain operations through private sales of equity securities.

The Company believes that in the near term its best prospect for returning its U.S. and consolidated operations to profitability is through the growth in sales of the ICL in the U.S. combined with continued growth in international markets. 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 2007.

The Company believes that as a result of its debt financings, along with expected cash from operations, it currently has sufficient cash to meet its funding requirements at least through the first quarter of 2008. However, given its history of losses and negative cash flows, it is possible that the Company will find it necessary to supplement these sources of capital with additional financing to sustain operations until the Company returns to profitability.

The credit facilities are subject to various financial covenants and if our losses continue, we risk defaulting on the terms of our credit facilities. Our limited borrowing capacity could cause a shortfall in working capital or prevent us from making expenditures to expand or enhance our business. A default on any of our loan agreements could cause our long term obligations to be accelerated, make further borrowing difficult and jeopardize our ability to continue operations.

If the Company is unable to rely solely on existing debt financing and 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 or debt securities.

The Company has filed a shelf registration statement with the Securities and Exchange Commission, which provides for the public offering and sale of up to \$15 million in debt or equity securities pursuant to the Securities Act of 1933, as amended. The registration statement became effective on August 8, 2006. The Company is not obligated to sell any amount of securities under the registration statement, and as of the date of this report it has not entered into any commitment to do so. Notwithstanding the availability of shelf registration, the Company's ability to raise financing through sales of securities depends on general market conditions and the demand for STAAR's common stock or debt securities. The conditions prevailing at the time the Company seeks to raise capital may prevent it from selling securities under the shelf registration on favorable terms, or at all. If our common stock has a low market price at a time when we sell equity securities, our existing shareholders could experience substantial dilution. 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.

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 largely depend on the success of the ICL, proceeds from option exercises, borrowings under the Company's bank credit facilities and proceeds from the private placement of common stock. Any withdrawal of support from its banks could have serious consequences on the Company's liquidity. The Company's liquidity also depends, 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 affect 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

Table of Contents

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.

Non-GAAP Measures

The following financial measures included below are not prepared in accordance with GAAP: Cash Usage and Standard Margin. A reconciliation of these non-GAAP financial measures to the most directly comparable GAAP measures is presented as a table below. Non-GAAP financial measures should not be considered a substitute for, or superior to, measures of financial performance prepared in accordance with GAAP.

Cash Usage The Cash Usage financial measure is not prepared in conformity with GAAP and excludes the purchase and sale of short-term investments from cash used in investing activities and net proceeds from private placement from cash provided by financing activities. Cash Usage is not a measurement of liquidity under GAAP and should not be considered as an alternative to net income, operating income, cash used in investing activities, cash provided by financing activities, or the change in cash and cash equivalents on the Consolidated Balance Sheets and may not be comparable with Cash Usage as defined by other companies.

The Company's Cash Usage of \$4,800,000 during fiscal 2006 is 52% below the Company's Cash Usage of \$9,978,000 compared with the same period of 2005.

	Fiscal Year Ended	
	December 29, 2006	December 30, 2005
Increase (decrease) in Cash and Cash Equivalents	\$ (4,950)	\$ 8,521
Add: purchase of short-term investments	193	15,300
Deduct: sale of short-term investments	(43)	(20,425)
Deduct: net proceeds from private placement		(13,374)
Cash Usage	\$ (4,800)	\$ (9,978)

Standard Margin Standard Margin is not a GAAP financial measure. Standard Margin represents the margin associated with the direct costs of production and excludes other cost of sales. Included in other costs of sales are the following: distribution costs, royalty expense, inventory provisions and all other cost of goods sold. Standard Margin should not be considered an alternative to gross profit margin and may not be comparable with Standard Margin as defined by other companies.

The Company's Standard Margin for 2006 was 53.9%, an increase of 1.2% compared with 2005.

	Fiscal Year Ended	
	December 29, 2006	December 30, 2005
Gross Profit Margin	47.0%	46.4%
Add: distribution costs	1.4%	1.6%
Add: royalty expense	0.9%	0.7%

Add: inventory provisions	3.2%	2.1%
Add: all other cost of sales	1.4%	1.9%
Standard Margin	53.9%	52.7%

Management believes Cash Usage and Standard Margin financial information provides meaningful supplemental information regarding our performance and liquidity by excluding the items described above in order to show the Cash Usage and Standard Margin from normal operations. STAAR believes that this financial information is useful to our management and investors in assessing STAAR's historical performance and liquidity and when planning, forecasting and analyzing future periods.

Table of Contents

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 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 Company's products are marketed to ophthalmic surgeons, hospitals, ambulatory surgery centers or vision centers, and distributors. IOLs may be offered to surgeons and hospitals on a consignment basis. In accordance with SAB 104, the Company recognizes revenue for consignment inventory when the IOL is implanted during surgery and not upon shipment to the surgeon. 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 assessments of the adequacy of the reserves for uncollectible accounts.

Stock-Based Compensation. We account for the issuance of stock options to employees and directors in accordance with SFAS 123R and the issuance of stock options and warrants for services from non-employees in accordance with SFAS 123, Accounting for Stock-Based Compensation, and the Financial Accounting Standards Board (FASB) Emerging Issues Task Force Issue (EITF) No. 96-18, Accounting For Equity Instruments That Are Issued To Other Than Employees For Acquiring Or In Conjunction With Selling Goods Or Services, by estimating the fair value of options and warrants issued using the Black-

Table of Contents

Scholes pricing model. This model's calculations include the exercise price, the market price of shares on grant date, risk-free interest rates, expected life of the option or warrant, expected volatility of our stock and expected dividend yield. The amounts recorded in the financial statements for share-based expense could vary significantly if we were to use different assumptions.

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 29, 2006, the valuation allowance fully offsets the value of deferred tax assets on the Company's balance sheet. Net increases to the valuation allowance were \$6,774,000, \$5,490,000 and \$6,097,000 in 2006, 2005 and 2004, 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.

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

Table of Contents

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 for the year ended December 29, 2006, 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 for the year ended December 29, 2006, and no impairment was identified. As of December 29, 2006, 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 \$7.0 million as of December 29, 2006. 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. The Company reviews patents and licenses for impairment in the same assessment discussed above in the discussion above regarding *Impairment of Long-Lived Assets*. No impairment was identified during the review completed in the fourth quarter of 2006.

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 had 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.

Table of Contents**Recent Accounting Pronouncements**

In June 2006, the FASB issued FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes*, (FIN 48) which clarifies the accounting for uncertainty in income taxes. FIN 48 requires that companies recognize in the consolidated financial statements the impact of a tax position, if that position is more likely than not of being sustained on audit, based on the technical merits of the position. FIN 48 also provides guidance on de-recognition, classification, interest and penalties, accounting in interim periods and disclosure. The provisions of FIN 48 are effective for fiscal years beginning after December 15, 2006. We will adopt FIN 48 effective January 1, 2007. We are currently evaluating the effect of this new pronouncement.

In September 2006, the FASB issued SFAS No. 157 *Fair Value Measurements* (SFAS 157). SFAS 157 provides a new single authoritative definition of fair value and provides enhanced guidance for measuring the fair value of assets and liabilities and requires additional disclosures related to the extent to which companies measure assets and liabilities at fair value, the information used to measure fair value, and the effect of fair value measurements on earnings. SFAS 157 is effective for the Company as of December 29, 2007. The Company is currently assessing the impact, if any, of SFAS 157 on its consolidated financial statements.

In November 2006, the FASB issued FASB Staff Position No. EITF 00-19-2, *Accounting for Registration Payment Arrangements* , which specifies that the contingent obligation to make future payments or otherwise transfer consideration under a registration payment arrangement, whether issued as a separate agreement or included as a provision of a financial instrument or other agreement, should be separately recognized and measured. Additionally, this guidance further clarifies that a financial instrument subject to a registration payment arrangement should be accounted for in accordance with other applicable GAAP without regard to the contingent obligation to transfer consideration pursuant to the registration payment arrangement. This guidance is effective for financial statements issued for fiscal years beginning after December 15, 2006, and interim periods within those fiscal years. We are assessing the impact of adopting EITF 00-19-2 and currently do not believe the adoption will have a material impact on our consolidated financial statements.

In February 2007, the FASB issued Statement No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities* (SFAS 159). SFAS 159 provides that companies may elect to measure specified financial instruments and warranty and insurance contracts at fair value on a contract-by-contract basis, with changes in fair value recognized in earnings each reporting period. The election, called the fair value option, will enable some companies to reduce the variability in reported earnings caused by measuring related assets and liabilities differently. Companies may elect fair-value measurement when an eligible asset or liability is initially recognized or when an event, such as a business combination, triggers a new basis of accounting for that asset or liability. The election is irrevocable for every contract chosen to be measured at fair value and must be applied to an entire contract, not to only specified risks, specific cash flows, or portions of that contract. SFAS 159 is effective as of the beginning of a company's first fiscal year that begins after November 15, 2007. Retrospective application is not allowed. Companies may adopt SFAS 159 as of the beginning of a fiscal year that begins on or before November 15, 2007 if the choice to adopt early is made after SFAS 159 has been issued and within 120 days of the beginning of the fiscal year of adoption and the entity has not issued GAAP financial statements for any interim period of the fiscal year that includes the early adoption date. Companies are permitted to elect fair-value measurement for any eligible item within SFAS 159's scope at the date they initially adopt SFAS 159. The adjustment to reflect the difference between the fair value and the current carrying amount of the assets and liabilities for which a company elects fair-value measurement is reported as a cumulative-effect adjustment to the opening balance of retained earnings upon adoption. Companies that adopt SFAS 159 early must also adopt all of SFAS 157's requirements at the early adoption date. We are assessing the impact of adopting SFAS 159 and currently do not believe the adoption will have a material impact on our consolidated financial statements.

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

Table of Contents

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 \$1.8 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 Swiss 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 \$18,000.

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 29, 2006, 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 and the identification of the material weakness in internal controls over financial reporting described below, 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 were not 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.

As previously reported in Form 8-Ks filed on January 23, 2007 and March 14, 2007, the Audit Committee of the Company's Board of Directors commenced in January 2007, an independent investigation into reports to the Company's management by Guenther Roepstorff, president of Domilens GmbH, a subsidiary of STAAR located in Germany, that he admitted to the German Federal Ministry of Finance that without STAAR's knowledge he had

Table of Contents

diverted property of Domilens with a book value of approximately \$400,000 to a company under his control over a four-year period between 2001 and 2004. Mr. Roepstorff made this admission in connection with an audit conducted by the Ministry in 2006, which examined the financial records of Mr. Roepstorff, Domilens and the company to which he diverted the property, Equimed GmbH (currently known as eyemaxx GmbH), covering the four-year period. During the course of the investigation, the Company found that in addition to the diversions of property admitted by Mr. Roepstorff, payments were made to Mr. Roepstorff disguised as prepayments to suppliers and unauthorized borrowing occurred.

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.

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

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 29, 2006, 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.

A material weakness is a control deficiency, or a combination of control deficiencies that results in more than a remote likelihood that a material misstatement of annual or interim financial statements will not be prevented or detected. In connection with the assessment described above, management has identified the following material weakness as of December 29, 2006:

Failure to design and maintain controls over and in its German subsidiary sufficient to detect and prevent management override and fraud

Control Environment The Company did not maintain an effective control environment because of the following: (a) the Company did not adequately and consistently reinforce the importance of adherence to controls and the Company's code of conduct; (b) the Company failed to institute all elements of an effective program to help prevent and detect fraud by Company employees; and (c) the Company did not maintain

effective corporate and regional management oversight and monitoring of operations to detect managements override of established financial controls and accounting policies, execution of improper transactions and accounting entries to impact revenue and earnings, and reporting of these transactions to the appropriate finance personnel or the Company s independent registered public accounting firm.

As a result of the material weakness described above, management has concluded that our internal control over financial reporting was not effective as of the end of the fiscal year ended December 29, 2006.

Table of Contents

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.

Remediation of Material Weakness in Internal Control Over Financial Reporting

The Company has engaged in, and will continue to engage in remediation efforts to address the material weakness in its internal control over financial reporting. Specific actions which have been or will be taken are outlined below:

The Company has:

- obtained the immediate resignation of the president of Domilens GmbH

- appointed the V.P. Sales and Marketing International, as interim president of Domilens

- enhanced monitoring and oversight from STAAR's Swiss and U.S. operations

- held meetings to discuss the Company's Code of Ethics and whistleblower policies with subsidiary employees as a bridge to more formal training

The Company will assess the need to take additional actions including but not limited to the following:

- assign oversight of corporate compliance programs and training to its corporate legal counsel

- evaluate accounting and inventory systems to identify opportunities for enhanced controls

- recruit a local controller who will have enhanced authority in Domilens and direct reporting to corporate headquarters

- evaluate the need for other employee changes

- re-educate employees in STAAR's Code of Ethics

- enhance whistleblower program

- expand executive management's ongoing communications regarding the importance of adherence to internal controls and company policies

- reinforce the certification process to emphasize senior manager's accountability for maintaining an ethical environment

- take steps to fully integrate Domilens into the controls environment of STAAR and STAAR AG

- implement an internal auditing function at STAAR and its subsidiaries, including Domilens

- standardize accounting policies and procedures globally

evaluate and standardize SOX testing and controls

institute global fraud prevention programs

evaluate such other actions as its advisors may recommend

Changes in Internal Control over Financial Reporting

There was no change during the fiscal quarter ended December 29, 2006, 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.

Table of Contents

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 29, 2006.

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*

- (1) Financial statements required by Item 15 of this form are filed as a separate part of this report following Part IV:

<u>Report of Independent Registered Public Accounting Firm</u>	F-2
<u>Report of Independent Registered Public Accounting Firm</u>	F-3
<u>Consolidated Balance Sheets at December 29, 2006 and at December 30, 2005</u>	F-5
<u>Consolidated Statements of Operations for the years ended December 29, 2006, December 30, 2005, and December 31, 2004</u>	F-6
<u>Consolidated Statements of Changes in Stockholders' Equity and Comprehensive Loss for the years ended December 29, 2006, December 30, 2005, and December 31, 2004</u>	F-7
	F-8

Consolidated Statements of Cash Flows for the years ended December 29, 2006, December 30, 2005, and December 31, 2004

Notes to Consolidated Financial Statements

F-9

(2) Schedules required by Regulation S-X are filed as an exhibit to this report:

I. Independent Registered Public Accounting Firm Report on Schedule

F-31

II. Schedule II Valuation and Qualifying Accounts and Reserves

F-32

Table of Contents

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(1)
- 3.2 By-laws, as amended to date(1)
 - 4.1 1991 Stock Option Plan of STAAR Surgical Company(2)
 - 4.2 1996 STAAR Surgical Company Non-Qualified Stock Plan(3)
 - 4.3 1998 STAAR Surgical Company Stock Plan, adopted April 17, 1998(4)
- 4.4 Form of Certificate for Common Stock, par value \$0.01 per share(11)
- 4.5 2003 Omnibus Equity Incentive Plan and form of Option Grant and Stock Option Agreement(10)
- 4.6 Registration Rights Agreement, dated June 4, 2004(15)
- 4.7 Registration Rights Agreement, dated March 31, 2005(18)
- 10.1 Joint Venture Agreement, dated May 23, 1988, among the Company, Canon Marketing Japan 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 Marketing Japan Inc., and Canon Staar Company, Inc. dated September 28, 2001(8)
- 10.3 Indenture of Lease dated September 1, 1993, between the Company and FKT Associates and First through Third Additions Thereto(7)
- 10.4 Second Amendment to Indenture of Lease dated September 21, 1998, between the Company and FKT Associates(7)
- 10.5 Third Amendment to Indenture of Lease dated October 13, 2003, by and between the Company and FKT Associates(13)
- 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(13)
- 10.9 Amendment No. 1 to Standard Industrial/Commercial Multi-Tenant Lease dated January 3, 2003, by and between the Company and California Rosen(13)
- 10.10 Lease Agreement dated July 12, 1994, between STAAR Surgical AG and Calderari and Schwab AG/SA(17)
- 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(17)
- 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(17)
- 10.13 Commercial Lease Agreement dated November 29, 2000, between Domilens GmbH and DePfa Deutsche Pfandbriefbank AG(17)
- 10.14 Patent License Agreement, dated May 24, 1995, with Eye Microsurgery Intersectoral Research and Technology Complex(12)
- 10.15 Patent License Agreement, dated January 1, 1996, with Eye Microsurgery Intersectoral Research and Technology Complex(7)
 - 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)

Table of Contents

- 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(17)
- 10.30 Stock Option Certificate dated May 30, 2002, between the Company and Volker Anhaeusser(17)
- 10.31 Stock Option Agreement dated November 13, 2001, between the Company and David R. Morrison(8)
- 10.32 Stock Option Certificate dated February 13, 2003, between the Company and Donald Duffy(17)
- 10.36 Offer of Employment dated July 12, 2002, from the Company to Nick Curtis(17)
- 10.37 Amendment to Offer of Employment dated February 14, 2003 from the Company to Nick Curtis(17)
- 10.38 Stock Option Certificate dated February 14, 2003, between the Company and Nicholas Curtis(17)
- 10.39 Amended and Restated Stock Option Certificate dated February 12, 2003, between the Company and Nicholas Curtis(17)
- 10.40 Employment Agreement dated March 18, 2005, between the Company and Tom Paul(17)
- 10.42 Form of Indemnification Agreement between the Company and certain officers and directors(17)
- 10.43 Managing Director s Contract of Employment, dated June 22, 1993, between Domilens and Guenther Roepstorff(17)
- 10.44 Supplementary Agreement #1 to the Managing Director s Contract of Employment, dated November 25, 1997, between STAAR Surgical AG and Guenther Roepstorff(17)
- 10.45 Supplementary Agreement #2 to the Managing Director s Contract of Employment dated January 1, 1998, between Domilens and Guenther Roepstorff(17)
- 10.46 Supplementary Agreement #3 to the Managing Director s Contract of Employment dated January 1, 2003, between Domilens and Guenther Roepstorff(17)
- 10.47 Employment Agreement dated May 5, 2004, between the ConceptVision Australia Pty Limited CAN 006 391 928 and Philip Butler Stoney(14)
- 10.48 Employment Agreement dated May 5, 2004, between the ConceptVision Australia Pty Limited CAN 006 391 928 and Robert William Mitchell(14)
- #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(9)
- 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(14)
- 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(14)
- 10.53 Stock Purchase Agreement dated June 4, 2004(15)
- 10.54 Master Credit Agreement dated August 2, 2004, between STAAR Surgical AG and UBS AG(16)
- 10.58 Loan Agreement between Deutsche Postbank AG and Domilens GmbH dated August 30, 2005(19)
- 10.59 Standard Industrial/Commercial Multi Tenant Lease Gross dated October 6, 2005, entered into between the Company and Z & M LLC(19)
- 10.60 Stock Purchase Agreement dated March 31, 2005(18)
- 10.61 Amendment No. 1 to Commercial Leases between Domilens GmbH and DePfa Deutsche Pfandbriefbank AG related to Domilens headquarters facilities, dated as of December 13, 2005. (23)
- #10.62 Credit and Security Agreement by and between STAAR Surgical Company and Wells Fargo Bank, National Association acting through its Wells Fargo Business Credit Operating Division, dated June 8, 2006. (24)
- 10.63 Promissory Note between STAAR Surgical Company and Broadwood Partners, L.P., dated March 21, 2007. (25)
- 10.64

Warrant Agreement between STAAR Surgical Company and Broadwood Partners, L.P., dated March 21, 2007. (25)

Table of Contents

- 14.1 Code of Ethics(17)
- 21.1 List of Significant Subsidiaries(17)
- 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 Current Report on Form 8-K, as filed on May 23, 2006.
- (2) Incorporated by reference from the Company's Registration Statement on Form S-8, File No. 033-76404, as filed on March 11, 1994.
- (3) Incorporated by reference from the Company's Annual Report on Form 10-K, for the year ended January 3, 1997, as filed on April 2, 1997.
- (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 29, 2000, as filed on March 29, 2001.
- (8) 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.
- (9) 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.
- (10) 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.
- (11)

Edgar Filing: STAAR SURGICAL CO - Form 10-K

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.

- (12) 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.
- (13) 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.
- (14) Incorporated by reference to the Company's Quarterly Report, for the period ended April 2, 2004, as filed on May 12, 2004.
- (15) Incorporated by reference to the Company's Current Report on Form 8-K filed on June 9, 2004.
- (16) Incorporated by reference to the Company's Quarterly Report, for the period ended October 1, 2004, as filed on November 10, 2004.
- (17) Incorporated by reference to the Company's Annual Report on Form 10-K, for the year ended December 30, 2005, as filed on March 30, 2005.
- (18) Incorporated by reference to the Company's Current Report on Form 8-K filed on April 5, 2005.

Table of Contents

- (19) Incorporated by reference to the Company's Quarterly Report for the period ended September 30, 2005, as filed on November 9, 2005.
- (20) Incorporated by reference to the Company's Quarterly Report for the period ended March 31, 2006, as filed on May 10, 2006.
- (20) Incorporated by reference to the Company's Current Report on Form 8-K filed on June 14, 2006.
- (21) Incorporated by reference to the Company's Current Report on Form 8-K filed on March 21, 2007.

Table of Contents**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 29, 2007

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.

Name	Title	Date
/s/ David Bailey David Bailey	President, Chief Executive Officer and Director (principal executive officer)	March 29, 2007
/s/ Deborah Andrews Deborah Andrews	Chief Financial Officer (principal accounting and financial officer)	March 29, 2007
/s/ Don Bailey Don Bailey	Chairman of the Board, Director	March 29, 2007
/s/ Donald Duffy Donald Duffy	Director	March 29, 2007
/s/ David Morrison David Morrison	Director	March 29, 2007
/s/ David Schlotterbeck David Schlotterbeck	Director	March 29, 2007

Table of Contents

STAAR SURGICAL COMPANY AND SUBSIDIARIES

CONSOLIDATED FINANCIAL STATEMENTS

**Years Ended December 29, 2006,
December 30, 2005 and December 31, 2004**

TABLE OF CONTENTS

<u>Report of Independent Registered Public Accounting Firm</u>	F-2
<u>Report of Independent Registered Public Accounting Firm</u>	F-3
<u>Consolidated Balance Sheets at December 29, 2006 and at December 30, 2005</u>	F-5
<u>Consolidated Statements of Operations for the years ended December 29, 2006, December 30, 2005, and December 31, 2004</u>	F-6
<u>Consolidated Statements of Changes in Stockholders' Equity and Comprehensive Loss for the years ended December 29, 2006, December 30, 2005, and December 31, 2004</u>	F-7
<u>Consolidated Statements of Cash Flows for the years ended December 29, 2006, December 30, 2005, and December 31, 2004</u>	F-8
<u>Notes to Consolidated Financial Statements</u>	F-9

F-1

Table of Contents

**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 (the Company) as of December 29, 2006 and December 30, 2005, and the related consolidated statements of operations, changes in stockholders' equity and comprehensive loss, and cash flows for each of the three years in the period ended December 29, 2006. 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 29, 2006 and December 30, 2005, and the consolidated results of their operations and their cash flows for each of the three years in the period ended December 29, 2006, in conformity with accounting principles generally accepted in the United States of America.

As more fully disclosed in Note 10 to the consolidated financial statements, effective December 31, 2005, the Company adopted the provisions of Statement of Financial Accounting Standards No. 123(R), Share-Based Payment.

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 29, 2006, based on criteria established in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) and our report dated March 29, 2007 expressed an unqualified opinion on management's assessment of the effectiveness of internal control over financial reporting and an adverse opinion on the effectiveness of internal control over financial reporting.

/s/ BDO Seidman, LLP

Los Angeles, California
March 29, 2007

Table of Contents

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 Item 9A, *Management's Report on Internal Control over Financial Reporting*, that STAAR Surgical Company and Subsidiaries (the Company) did not maintain effective internal control over financial reporting as of December 29, 2006, because of the effect of management's failure to design and maintain controls over and in its German subsidiary sufficient to detect and prevent management override and fraud, based on criteria established in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). The 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.

A material weakness is a control deficiency, or a combination of control deficiencies, that results in more than a remote likelihood that a material misstatement of the annual or interim financial statements will not be prevented or detected. The following material weakness has been identified and included in management's assessment. Management did not design and maintain controls over and in its German subsidiary sufficient to detect and prevent management override and fraud. This material weakness was considered in determining the nature, timing, and extent of audit tests applied in our audit of the 2006 financial statements, and this report does not affect our report dated March 29, 2007 on those consolidated financial statements.

In our opinion, management's assessment that STAAR Surgical Company and Subsidiaries did not maintain effective internal control over financial reporting as of December 29, 2006, is fairly stated, in all material respects, based on the COSO criteria. Also in our opinion, because of the effect of the material weakness described above on the achievement of the objectives of the control criteria, the Company has not maintained effective internal control over financial reporting as of December 29, 2006, based on the COSO criteria.

F-3

Table of Contents

We do not express an opinion or any form of assurance on management's statements referring to corrective actions taken by the Company after the date of management's assessment.

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 29, 2006 and December 30, 2005 and the related consolidated statements of operations, changes in stockholders' equity and comprehensive loss, and cash flows for each of the three years in the period ended December 29, 2006, and our report dated March 29, 2007 expressed an unqualified opinion thereon.

/s/ BDO Seidman, LLP

Los Angeles, California
March 29, 2007

F-4

Table of Contents**STAAR SURGICAL COMPANY AND SUBSIDIARIES****CONSOLIDATED BALANCE SHEETS
December 29, 2006 and December 30, 2005**

	2006	2005
	(In thousands, except par value amounts)	
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 7,758	\$ 12,708
Short-term investments restricted	150	
Accounts receivable trade, net	6,524	5,100
Inventories	12,939	14,699
Prepays, deposits and other current assets	1,923	1,763
Total current assets	29,294	34,270
Investment in joint venture	397	283
Property, plant and equipment, net	5,846	5,595
Patents and licenses, net	4,439	4,920
Goodwill	7,534	7,534
Other assets	260	153
Total assets	\$ 47,770	\$ 52,755
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Notes payable	\$ 1,802	\$ 1,676
Accounts payable	5,055	4,014
Obligations under capital leases current	500	36
Other current liabilities	7,574	5,809
Total current liabilities	14,931	11,535
Obligations under capital leases long-term	957	116
Other long-term liabilities	122	738
Total liabilities	16,010	12,389
Commitments and contingencies (Note 11)		
Stockholders equity:		
Preferred stock, \$.01 par value, 10,000 shares authorized, none issued or outstanding		
Common stock, \$.01 par value; 60,000 and 30,000 shares authorized; issued and outstanding 25,618 and 24,819 shares	256	248
Additional paid-in capital	117,312	112,434
Accumulated other comprehensive income	889	146

Accumulated deficit	(86,697)	(71,653)
Notes receivable from former director, net	31,760	41,175 (809)
Total stockholders' equity	31,760	40,366
Total liabilities and stockholders' equity	\$ 47,770	\$ 52,755

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

F-5

Table of Contents**STAAR SURGICAL COMPANY AND SUBSIDIARIES****CONSOLIDATED STATEMENTS OF OPERATIONS****Years Ended December 29, 2006, December 30, 2005 and December 31, 2004**

	2006	2005	2004
	(In thousands, except per share amounts)		
Net sales	\$ 56,282	\$ 51,303	\$ 51,685
Cost of sales	29,849	27,517	25,542
Gross profit	26,433	23,786	26,143
Selling, general and administrative expenses:			
General and administrative	10,891	9,727	9,253
Marketing and selling	22,395	18,552	20,302
Research and development	7,080	5,573	6,246
Note reserves (reversals)	(331)	746	500
Total selling, general and administrative expenses	40,035	34,598	36,301
Operating loss	(13,602)	(10,812)	(10,158)
Other income (expense):			
Equity in operations of joint venture	114	158	(191)
Interest income	293	453	219
Interest expense	(261)	(170)	(215)
Other income (expense), net	(51)	413	99
Total other income (expense), net	95	854	(88)
Loss before income taxes and minority interest	(13,507)	(9,958)	(10,246)
Provision for income taxes	1,537	1,239	1,057
Minority interest		(22)	29
Net loss	\$ (15,044)	\$ (11,175)	\$ (11,332)
Loss per share:			
Basic and diluted	\$ (0.60)	\$ (0.47)	\$ (0.58)
Weighted average shares outstanding			
Basic and diluted	25,227	23,704	19,602

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

Table of Contents**STAAR SURGICAL COMPANY AND SUBSIDIARIES****CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
AND COMPREHENSIVE LOSS****Years Ended December 29, 2006, December 30, 2005 and December 31, 2004**

	Common Stock Shares	Common Stock Par Value	Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss) (In thousands)	Accumulated Deficit	Notes Receivable	Total
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							(10,880)
Common stock issued upon exercise of warrants	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							(12,053)
Common stock issued upon exercise of options	36		130				130
Common stock issued as payment for services	13		77				77
			203				203

Stock-based consultant expense							
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	24,819	248	112,434	146	(71,653)	(809)	40,366
Net loss					(15,044)		(15,044)
Foreign currency translation adjustment				743			743
Total comprehensive loss							(14,301)
Common stock issued upon exercise of options	753	8	2,882				2,890
Stock-based compensation			1,996				1,996
Restricted stock grants	46						
Proceeds from notes receivable, net						1,181	1,181
Accrued interest on notes receivable						(41)	(41)
Notes receivable reserve reversal						(331)	(331)
Balance, at December 29, 2006	25,618	\$ 256	\$ 117,312	\$ 889	\$ (86,697)	\$	\$ 31,760

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

Table of Contents**STAAR SURGICAL COMPANY AND SUBSIDIARIES****CONSOLIDATED STATEMENTS OF CASH FLOWS****Years Ended December 29, 2006, December 30, 2005 and December 31, 2004**

	2006	2005	2004
	(In thousands)		
Cash flows from operating activities:			
Net loss	\$ (15,044)	\$ (11,175)	\$ (11,332)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation of property and equipment	1,891	1,992	2,005
Amortization of intangibles	481	480	688
Loss on disposal of fixed assets	169	85	175
Equity in earnings of joint venture	(114)	(158)	191
Stock-based compensation expense	1,841	203	231
Common stock issued for services		77	60
Notes receivable reserve (reversal)	(331)	746	500
Deferred income taxes	179		
Other	(44)	(81)	(95)
Minority interest		(22)	21
Changes in working capital:			
Accounts receivable	(1,400)	1,117	(542)
Inventories	1,896	270	(2,282)
Prepays, deposits and other current assets	(160)	206	32
Accounts payable	1,042	(1,399)	769
Other current liabilities	947	683	775
Net cash used in operating activities	(8,647)	(6,976)	(8,804)
Cash flows from investing activities:			
Acquisition of property and equipment	(779)	(1,194)	(1,705)
Acquisition of patents and licenses			(16)
Purchase of short-term investments	(193)	(15,300)	(8,000)
Sale of short-term investments	43	20,425	2,875
Purchase of minority interest in subsidiary			(768)
Proceeds from notes receivable	1,181	130	330
Net change in other assets	(107)	16	(91)
Dividends received from joint venture			81
Net cash provided by (used in) investing activities	145	4,077	(7,294)
Cash flows from financing activities:			
Net borrowings (payments) under notes payable and long-term debt	(81)	(1,206)	72
Proceeds from the exercise of stock options and warrants	2,890	130	829
Net proceeds from private placement		13,374	11,646
Net cash provided by financing activities	2,809	12,298	12,547

Edgar Filing: STAAR SURGICAL CO - Form 10-K

Effect of exchange rate changes on cash and cash equivalents	743	(878)	452
Increase (decrease) in cash and cash equivalents	(4,950)	8,521	(3,099)
Cash and cash equivalents, at beginning of year	12,708	4,187	7,286
Cash and cash equivalents, at end of year	\$ 7,758	\$ 12,708	\$ 4,187

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

F-8

Table of Contents

STAAR SURGICAL COMPANY AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Years Ended December 29, 2006 and December 30, 2005

Note 1 Significant Accounting Policies

Organization and Description of Business

STAAR Surgical Company and Subsidiaries (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 Collamer IOLs, the ICL and the AquaFlow device. STAAR Surgical AG also controls 100% of Domilens GmbH, a German sales subsidiary, which distributes both STAAR products and products from other ophthalmic manufacturers.

Canon Staar Joint Venture

In 1988, the Company entered into a Joint Venture Agreement with Canon Inc. and Canon Marketing Japan 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 Marketing, 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 Marketing 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.

F-9

Table of Contents

STAAR SURGICAL COMPANY AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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 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 Marketing 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.

Investment in the Company's joint venture, Canon Staar Co., Inc., is accounted for using the equity method of accounting (see Note 7).

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.

Foreign Currency

In accordance with SFAS No 52, *Foreign Currency Translation*, 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 2006, 2005 and 2004, the net foreign translation gain (loss) was \$743,000, (\$878,000) and \$452,000, respectively, and net foreign currency transaction gain (loss), included in the statement of operations in other income (expense), net, was (\$65,000), \$334,000 and (\$190,000), respectively.

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 Company's products are marketed to ophthalmic surgeons, hospitals, ambulatory surgery centers or vision centers, and distributors. IOLs may be offered to surgeons and hospitals on a consignment basis. In accordance with SAB 104,

the Company recognizes revenue for consignment inventory when the IOL is implanted during surgery and not upon shipment to the surgeon.

The Company has ongoing programs that, under specified conditions, allow customers to return products and, in accordance with SFAS No. 48, *Revenue Recognition When Right of Return Exists*, records liabilities for estimated returns and allowances at the time revenue is recognized. The Company's liability for estimated returns considers historical trends, the impact of new product launches, the entry of a competitor, product rationalization and the various terms and arrangements offered, including sales with extended credit terms.

Table of Contents

STAAR SURGICAL COMPANY AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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 customers and maintains a provision for estimated credit losses based upon its historical experience and any specific customer collection issues that have been identified.

Use of Estimates

The consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America and, as such, include amounts based on informed estimates and judgments of management with consideration given to materiality. For example, estimates are used in determining valuation allowances for uncollectible trade receivables, obsolete inventory, deferred income taxes and tax reserves. Estimates are also used in the evaluation of asset impairment, in determining the useful life of depreciable assets, and in calculating stock-based compensation. Actual results could differ from those estimates.

Segment Reporting

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 16).

Cash and Cash Equivalents

The Company considers all highly liquid investments purchased with a maturity of three months or less to be cash equivalents. The Company maintains cash deposits with major banks which from time to time may exceed federally insured limits. The Company periodically assesses the financial condition of the institutions and believes that the risk of any loss is minimal.

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.

Fair Value of Financial Instruments

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

Inventories

Inventories are valued at the lower of cost, determined on a first-in, first-out basis, or market. Inventories include the costs of raw material, labor, and manufacturing overhead. 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 to properly reflect inventory at the lower of cost or market.

F-11

Table of Contents

STAAR SURGICAL COMPANY AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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. Leasehold improvements are amortized over the lesser of the estimated useful lives of the assets or the related lease term. Major improvements are capitalized and minor replacements, maintenance and repairs are charged to expense as incurred.

Demonstration Equipment

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

Goodwill and Other Intangible Assets

Goodwill represents the excess of the purchase price over the fair value of identifiable net assets acquired in business combinations accounted for as purchases. The Company 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 2006 and no impairment was identified. As of December 29, 2006, 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 \$7.0 million and \$6.6 million as of December 29, 2006 and December 30, 2005, respectively. The Company capitalizes the costs of acquiring patents and licenses. Amortization is computed on the straight-line basis over the estimated useful lives, since the pattern in which the economic benefits realized cannot be precisely determined, which are based on legal and contractual provisions, and range from 10 to 20 years. Aggregate amortization expense for amortized other intangible assets was \$481,000, \$480,000 and \$688,000 for the years ended December 29, 2006, December 30, 2005 and December 31, 2004, respectively.

Table of Contents**STAAR SURGICAL COMPANY AND SUBSIDIARIES****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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

Fiscal Year

2007	\$ 481
2008	481
2009	481
2010	380
2011	380
Total	\$ 2,203

Impairment of Long-Lived Assets

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

There were no impairments of long-lived assets identified during the years ended December 29, 2006, December 30, 2005, and December 31, 2004.

Research and Development Costs

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

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.

Basic and Diluted Loss Per Share

The consolidated financial statements include basic and diluted per share information. Basic per share information is calculated by dividing net loss by the weighted average number of shares outstanding. Diluted per share information is calculated by also considering the impact of potential common stock on both net income and the weighted number of shares outstanding. As the Company was in a loss position, potential common shares of 2.6 million, 3.9 million, and 3.1 million for the fiscal years ended December 29, 2006, December 30, 2005, and December 31, 2004, respectively, were excluded from the computation as the shares would have had an anti-dilutive effect.

F-13

Table of Contents**STAAR SURGICAL COMPANY AND SUBSIDIARIES****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Stock Based Compensation**

Effective December 31, 2005, the Company adopted the fair value recognition provisions of Statement of Financial Accounting Standards (SFAS) No. 123 (revised 2004), Share-Based Payment (SFAS 123R), using the modified prospective transition method and therefore has not restated results for prior periods. Under this transition method, stock-based compensation expense for fiscal 2006 includes compensation expense for all stock-based compensation awards granted prior to, but not yet vested as of December 30, 2005, based on the grant date fair value estimated in accordance with the original provision of SFAS No. 123, Accounting for Stock-Based Compensation (SFAS 123). Stock-based compensation expense for all stock-based compensation awards granted after December 30, 2005 is based on the grant-date fair value estimated in accordance with the provisions of SFAS 123R. The Company recognizes these compensation costs on a straight-line basis over the requisite service period of the award, which is generally the option vesting term of three to four years. Prior to the adoption of SFAS 123R, the Company recognized stock-based compensation expense in accordance with Accounting Principles Board (APB) Opinion No. 25,

Accounting for Stock Issued to Employees (APB 25). In March 2005, the Securities and Exchange Commission (the SEC) issued Staff Accounting Bulletin No. 107 (SAB 107) regarding the SEC 's interpretation of SFAS 123R and the valuation of share-based payments for public companies. The Company has applied the provisions of SAB 107 in its adoption of SFAS 123R. See Note 10 to the Consolidated Financial Statements for a further discussion of stock-based compensation.

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 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.

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):

	2006	2005	2004
Net loss	\$ (15,044)	\$ (11,175)	\$ (11,332)
Foreign currency translation adjustment	743	(878)	452
Comprehensive loss	\$ (14,301)	\$ (12,053)	\$ (10,880)

Recent Accounting Pronouncements

In June 2006, the FASB issued FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes*, (FIN 48) which clarifies the accounting for uncertainty in income taxes. FIN 48 requires that companies recognize in the consolidated financial statements the impact of a tax position, if that position is more likely than not of being sustained on audit, based on the technical merits of the position. FIN 48 also provides guidance on de-recognition, classification, interest and penalties, accounting in interim periods and disclosure. The provisions of FIN 48 are effective for fiscal years beginning after December 15, 2006. We will adopt FIN 48 effective January 1, 2007. We are currently evaluating the effect of this new pronouncement.

In September 2006, the FASB issued SFAS No. 157 *Fair Value Measurements* (SFAS 157). SFAS 157 provides a new single authoritative definition of fair value and provides enhanced guidance for measuring the fair value of assets and liabilities and requires additional disclosures related to the extent to which companies measure

Table of Contents

STAAR SURGICAL COMPANY AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

assets and liabilities at fair value, the information used to measure fair value, and the effect of fair value measurements on earnings. SFAS 157 is effective for the Company as of December 29, 2007. The Company is currently assessing the impact, if any, of SFAS 157 on its consolidated financial statements.

In November 2006, the FASB issued FASB Staff Position No. EITF 00-19-2, *Accounting for Registration Payment Arrangements*, which specifies that the contingent obligation to make future payments or otherwise transfer consideration under a registration payment arrangement, whether issued as a separate agreement or included as a provision of a financial instrument or other agreement, should be separately recognized and measured. Additionally, this guidance further clarifies that a financial instrument subject to a registration payment arrangement should be accounted for in accordance with other applicable GAAP without regard to the contingent obligation to transfer consideration pursuant to the registration payment arrangement. This guidance is effective for financial statements issued for fiscal years beginning after December 15, 2006, and interim periods within those fiscal years. We are assessing the impact of adopting EITF 00-19-2 and currently do not believe the adoption will have a material impact on our consolidated financial statements.

In February 2007, the FASB issued Statement No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities* (SFAS 159). SFAS 159 provides that companies may elect to measure specified financial instruments and warranty and insurance contracts at fair value on a contract-by-contract basis, with changes in fair value recognized in earnings each reporting period. The election, called the *fair value option*, will enable some companies to reduce the variability in reported earnings caused by measuring related assets and liabilities differently. Companies may elect fair-value measurement when an eligible asset or liability is initially recognized or when an event, such as a business combination, triggers a new basis of accounting for that asset or liability. The election is irrevocable for every contract chosen to be measured at fair value and must be applied to an entire contract, not to only specified risks, specific cash flows, or portions of that contract. SFAS 159 is effective as of the beginning of a company's first fiscal year that begins after November 15, 2007. Retrospective application is not allowed. Companies may adopt SFAS 159 as of the beginning of a fiscal year that begins on or before November 15, 2007 if the choice to adopt early is made after SFAS 159 has been issued and within 120 days of the beginning of the fiscal year of adoption and the entity has not issued GAAP financial statements for any interim period of the fiscal year that includes the early adoption date. Companies are permitted to elect fair-value measurement for any eligible item within SFAS 159's scope at the date they initially adopt SFAS 159. The adjustment to reflect the difference between the fair value and the current carrying amount of the assets and liabilities for which a company elects fair-value measurement is reported as a cumulative-effect adjustment to the opening balance of retained earnings upon adoption. Companies that adopt SFAS 159 early must also adopt all of SFAS 157's requirements at the early adoption date. We are assessing the impact of adopting SFAS 159 and currently do not believe the adoption will have a material impact on our consolidated financial statements.

Note 2 Short-Term Investments Restricted

Short-term investments consist of a 12-month Certificate of Deposit with a 4.5% interest rate to collateralize capital leases funded under a lease line of credit with Mazuma Capital Corporation (see Note 8).

Table of Contents**STAAR SURGICAL COMPANY AND SUBSIDIARIES****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Note 3 Accounts Receivable Trade**

Accounts receivable consisted of the following at December 29, 2006 and December 30, 2005 (in thousands):

	2006	2005
Domestic	\$ 2,880	\$ 2,066
Foreign	4,334	3,514
	7,214	5,580
Less allowance for doubtful accounts and sales returns	690	480
	\$ 6,524	\$ 5,100

Note 4 Inventories

Inventories consisted of the following at December 29, 2006 and December 30, 2005 (in thousands):

	2006	2005
Raw materials and purchased parts	\$ 690	\$ 859
Work in process	1,669	2,259
Finished goods	10,580	11,581
	\$ 12,939	\$ 14,699

Note 5 Prepaids, Deposits, and Other Current Assets

Prepaids, deposits, and other current assets consisted of the following at December 29, 2006 and December 30, 2005 (in thousands):

	2006	2005
Prepaids and deposits	\$ 1,455	\$ 1,367
Other current assets	468	396
	\$ 1,923	\$ 1,763

Note 6 Property, Plant and Equipment

Property, plant and equipment consisted of the following at December 29, 2006 and December 30, 2005 (in thousands):

	2006	2005
Machinery and equipment	\$ 13,053	\$ 12,174
Furniture and fixtures	5,985	5,498
Leasehold improvements	4,952	4,832
	23,990	22,504
Less accumulated depreciation and amortization	18,144	16,909
	\$ 5,846	\$ 5,595

Depreciation expense for each of the years ended December 29, 2006, December 30, 2005, and December 31, 2004 was approximately \$2.0 million.

Table of Contents**STAAR SURGICAL COMPANY AND SUBSIDIARIES****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Note 7 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 Marketing Japan 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.

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

	2006	2005
Current assets	\$ 6,507	\$ 5,679
Non-current assets	2,986	1,242
Current liabilities	1,143	1,025
Non-current liabilities	778	709
Net sales	10,368	9,656
Gross profit	5,461	5,171
Income from operations	483	460
Net Income loss	\$ 228	\$ 316

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

	2006	2005	2004
Joint venture net income (loss)	\$ 228	\$ 316	\$ (382)
Equity interest	50%	50%	50%
Equity in operations of joint venture	\$ 114	\$ 158	\$ (191)

The Company did not receive dividends during 2006 and 2005. Approximately \$81,000 of dividends were received during 2004.

The Company recorded sales of certain IOL products to CSC of approximately \$67,000, \$180,000 and \$185,000 in 2006, 2005 and 2004, respectively.

The Company purchased preloaded injectors from CSC in the amount of \$2.2 million, \$2.0 million, and \$1.7 million in 2006, 2005, and 2004, respectively.

The Company owed CSC \$702,000 and \$566,000 as of December 29, 2006 and December 30, 2005, respectively, for purchases of preloaded injectors.

Note 8 Notes Payable

The Company and its subsidiaries have credit facilities with different lenders to support operations in the U.S., Switzerland and Germany, respectively.

On June 8, 2006 the Company signed a Credit and Security agreement with Wells Fargo Bank for a revolving credit facility. The credit facility provides for borrowings of 85% of eligible accounts receivable with a maximum of \$3.0 million, carries an interest rate of prime plus 1.5%, and is secured by substantially all of the assets of the Company's U.S. operations. The term of the agreement is three years and it contains certain financial covenants relating to minimum calculated net worth, net loss, liquidity and restrictions on Company investments or loans to affiliates and investments in capital expenditures, which only apply if the Company borrows and/or maintains an outstanding advance. As of December 29, 2006, there were no borrowings outstanding. As the Company does not

Table of Contents

STAAR SURGICAL COMPANY AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

satisfy minimum financial covenants in its U.S. operations that are a condition to borrowing, no borrowings are available.

The Company's lease agreement with Farnam Street Financial, Inc., as amended on October 9, 2006, provides for purchases of up to \$1,500,000 of property, plant and equipment. In accordance with the requirements of SFAS 13 Accounting for Leases, purchases under this facility are accounted for as capital leases and have a three-year term. Under the agreement, the Company has the option to purchase any item of the leased property, at the end of the respective items lease terms, at a mutually agreed fair value. Approximately \$573,000 in borrowings were available under this facility as of December 29, 2006.

The Company's lease agreement with Mazuma Capital Corporation, as amended on August 16, 2006, provides for purchases of up to \$301,000 of property, plant and equipment. In accordance with the requirements of SFAS 13 Accounting for Leases, purchases under this facility are accounted for as capital leases and have a two-year term. The Company is required to open a certificate of deposit as collateral in STAAR Surgical Company's name at the underwriting bank for 50% of the assets funded by Mazuma. As of December 29, 2006, the Company had a certificate of deposit for approximately \$150,000 recorded as short-term investment restricted with a 12-month term at a fixed interest rate of 4.5%. The agreement also provides that the Company may elect to purchase any item of the leased property at the end of its lease term for \$1. No borrowings were available under this facility as of December 29, 2006.

The Company's Swiss credit agreement, as amended on August 2, 2004, provides for borrowings of up to 3.0 million Swiss Francs CHF (approximately \$2.5 million based on the rate of exchange on December 29, 2006) for use in the Company's Swiss operations, permits either fixed-term or current advances, and does not have a termination date. The interest rate on current advances is 6.25% and 6.0% per annum, respectively, at December 29, 2006 and December 30, 2005, plus a commission rate of 0.25% payable quarterly. There were no current advances outstanding at December 29, 2006. The base interest rate for fixed-term advances follows Euromarket conditions for loans of a corresponding term and currency plus an individual margin (5.0% at December 29, 2006 and 4.25% at December 30, 2005, respectively). Fixed-term borrowings outstanding under the note at December 29, 2006 and December 30, 2005, respectively, were CHF 2.2 million (approximately \$1.8 million based on the rate of exchange at December 29, 2006) and CHF 2.2 million (approximately \$1.7 million based on the rate of exchange on December 30, 2005). 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 German subsidiary entered into a credit agreement on August 30, 2005. The renewed credit agreement provides for borrowings of up to 100,000 EUR (\$131,000 at the rate of exchange on December 29, 2006), at a rate of 8.5% per annum and does not have a termination date. The credit facility is not secured. There were no borrowings outstanding as of December 29, 2006 and December 30, 2005.

The Company was in compliance with the covenants of these credit facilities as of December 29, 2006.

Table of Contents**STAAR SURGICAL COMPANY AND SUBSIDIARIES****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Note 9 Income Taxes**

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

	2006	2005	2004
Current tax provision:			
U.S. federal	\$	\$	\$
State	17	18	
Foreign	1,341	1,221	1,057
Total current provision	1,358	1,239	1,057
Deferred tax provision:			
U.S. federal and state			
Foreign	179		
Total deferred provision	179		
Provision for income taxes	\$ 1,537	\$ 1,239	\$ 1,057

As of December 29, 2006, the Company had \$89.4 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 2026.

The Company has net income taxes payable at December 29, 2006 and December 30, 2005 of \$830,000 and \$923,000, respectively. Included in the Company's foreign tax provision is approximately \$700,000 in additional taxes that may be assessed by the German Ministry of Finance pursuant the Domilens Investigation (see Note 12).

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

	2006		2005		2004	
Computed benefit for taxes based on income at statutory rate	\$ (4,592)	34.0%	\$ (3,386)	34.0%	\$ (3,484)	34.0%
Increase (decrease) in taxes resulting from:						
Permanent differences	210	(1.6)	19	(0.2)	36	(0.3)
State taxes, net of federal income tax benefit	11	(0.1)	12	(0.1)		(0.0)

Edgar Filing: STAAR SURGICAL CO - Form 10-K

Tax effect attributed to foreign operations	733	(5.4)	300	(3.0)	158	(1.5)
Other			29	(0.3)	7	(0.1)
Valuation allowance	5,175	(38.3)	4,265	(42.8)	4,340	(42.4)
Effective tax provision (benefit) rate	\$ 1,537	(11.4)%	\$ 1,239	(12.4)%	\$ 1,057	(10.3)%

The state tax provision is composed of an increase to the state deferred tax asset and corresponding increase to the valuation allowance of \$1,256,000, \$945,000, and \$1,010,000 for 2006, 2005 and 2004 respectively. This results in a total state tax provision of \$17,000 for 2006, \$18,000, for 2005 and zero state tax provision for 2004.

Undistributed earnings of the Company's foreign subsidiaries amounted to approximately \$13.7 million at December 29, 2006. 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

Table of Contents**STAAR SURGICAL COMPANY AND SUBSIDIARIES****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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.

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. Approximately \$179,000 in deferred tax liabilities are classified in other current liabilities in the 2006 Consolidated Balance Sheet. Significant components of the Company's deferred tax assets (liabilities) as of December 29, 2006 and December 30, 2005 are as follows (in thousands):

	2006	2005
Current deferred tax assets (liabilities):		
Allowance for doubtful accounts and sales returns	\$ 120	\$ 133
Inventory	675	663
Accrued vacation	238	260
State taxes	3	3
Deferred revenue		46
Accrued expenses	99	
Valuation allowance	(1,314)	(1,105)
Total current deferred tax liabilities	\$ (179)	\$
Non-current deferred tax assets (liabilities):		
Net operating loss and capital loss carryforwards	36,515	30,157
Business, foreign and AMT credit carryforwards	879	880
Depreciation and amortization	75	28
Notes receivable		517
Reserve for restructuring costs	464	511
Capitalized R&D	409	420
Contributions	89	44
Stock-based payments	691	
Valuation allowance	(39,122)	(32,557)
Total non-current deferred tax assets (liabilities)	\$	\$

SFAS No. 109, Accounting for Income Taxes (SFAS 109) requires that a valuation allowance be established when it is more likely than not that all or a portion of a deferred tax asset may not be realized. Cumulative losses weigh heavily in the assessment of the need for a valuation allowance. 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):

	2006	2005	2004
Domestic	\$ (15,824)	\$ (12,665)	\$ (12,887)
Foreign	2,317	2,707	2,641
	\$ (13,507)	\$ (9,958)	\$ (10,246)

F-20

Table of Contents**STAAR SURGICAL COMPANY AND SUBSIDIARIES****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Note 10 Stockholders Equity*****Common Stock***

During fiscal year 2006, the Company issued 46,000 shares of restricted stock to certain employees and a consultant in consideration for future services to the Company. As of December 29, 2006, none of the shares were vested.

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. During fiscal 2006, 2,039 of the shares 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.

Restricted shares are issued at fair market value on the date of grant, vest over a period of three or four years, and are subject to forfeiture until vested or the service period is terminated. Prior to 2006, the cost of the restricted stock was recorded as deferred equity compensation in Additional Paid-in Capital and amortized over the vesting period. Beginning in 2006, the amortization is included in stock-based compensation.

Stock Based Compensation

As of December 29, 2006, the Company has multiple share-based compensation plans, which are described below. The Company issues new shares upon option exercise once the optionee remits payment for the exercise price. The compensation cost that has been charged against income for the 2003 Omnibus Plan and the 1998 Stock Option Plan totaled \$1,725,000 for the fiscal year ended December 29, 2006, which included \$1,634,000, respectively, for the implementation of SFAS 123R, and \$91,000 for restricted stock grants. In addition, for the fiscal year ended December 29, 2006, there was \$116,000, of compensation cost charged against income for consultant stock options. There was no income tax benefit recognized in the income statement for share-based compensation arrangements as the Company fully offsets net deferred tax assets with a valuation allowance. In addition, the Company capitalized \$155,000 of SFAS 123R compensation to inventory for the fiscal year ended December 29, 2006 and recognizes those amounts as expense under in Cost of Sales as the inventory is sold. See the table below for comparative purposes of prior year amounts (in thousands, except per share data):

	Fiscal Year Ended		
	December 29, 2006	December 30, 2005	December 31, 2004
Net loss as reported	\$ (15,044)	\$ (11,175)	\$ (11,332)
Add: Stock-based compensation included in reported net loss	1,841	(1,038)	(739)
	(1,841)	(1,038)	(739)

Edgar Filing: STAAR SURGICAL CO - Form 10-K

Less: Stock-based compensation expense determined under
the fair-value method for all awards

Pro forma net loss	\$ (15,044)	\$ (12,213)	\$ (12,071)
Net loss per share, basic and diluted, as reported	\$ (.60)	\$ (.47)	\$ (.58)
Pro forma net loss, basic and diluted, as reported	N/A	\$ (.52)	\$ (.62)

F-21

Table of Contents

STAAR SURGICAL COMPANY AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Stock Option Plans

In fiscal year 2003, the Board of Directors approved the 2003 Omnibus Equity Incentive Plan (the 2003 Plan) authorizing awards of equity compensation, including options to purchase common stock and restricted shares of 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. Each year the number of shares reserved for issuance under the 2003 Plan is increased if necessary to provide that 2% of the total shares of common stock outstanding on the immediately preceding December 31 will be reserved for issuance. The 2003 Plan provides for various forms of stock-based incentives. To date, of the available forms of awards under the 2003 Plan, the Company has granted only stock options and restricted stock. Options under the plan are granted at fair market value on the date of grant, become exercisable over a three- or four-year period, or as determined by the Board of Directors, and expire over periods not exceeding 10 years from the date of grant. Certain option and share awards provide for accelerated vesting if there is a change in control (as defined in the 2003 Plan). Restricted stock grants under the 2003 Plan generally vest over a period of three or four years. Pursuant to the plan, options for 1,817,000 shares were outstanding at December 29, 2006 with exercise prices ranging between \$3.81 and \$11.24 per share. There were 52,000 shares of restricted stock outstanding at December 29, 2006.

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 common stock or awards of common stock. The options under the plan were granted at fair market value on the date of grant, become exercisable over a three-year period, and expire 10 years from the date of grant. Pursuant to this plan, options for 500,000 were outstanding at December 29, 2006, 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 options to purchase common stock or awards of common stock. Under the provisions of the plan, 1.0 million shares were reserved for issuance; however, the maximum number of shares authorized may be increased provided such action is in compliance with Article IV of the plan. During fiscal year 2001, pursuant to Article IV of the plan, the stockholders of the Company authorized an additional 1.5 million shares. Generally, options under the plan are granted at fair market value at the date of the grant, become exercisable over a three-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 945,000 were outstanding at December 29, 2006 with exercise prices ranging between \$2.96 and \$13.625 per share. No further awards may be made under this plan.

In fiscal year 1995, the Company adopted the 1995 Consultant Stock Plan, authorizing the granting of options to purchase common stock or awards of common stock. Generally, options under the plan were 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 95,000 shares were outstanding at December 29, 2006 with exercise prices ranging from \$1.70 to \$3.00 per share. No further awards may be made under this plan.

Under provisions of the Company's 1991 Stock Option Plan, 2.0 million shares were reserved for issuance. Generally, options under this plan were granted at fair market value at the date of the grant, become exercisable over a three-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 shares were outstanding at December 29, 2006 with exercise prices ranging from \$9.56 to \$10.18 per share. No further awards may be made under this plan.

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 shares were outstanding at December 29, 2006 with exercise prices ranging between \$9.375 and \$10.63.

F-22

Table of Contents**STAAR SURGICAL COMPANY AND SUBSIDIARIES****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

During the fiscal year ended December 29, 2006, officers, employees and others exercised 753,000 options from the 1995, 1996, 1998, non qualified and 2003 stock option plans at prices ranging from \$1.91 to \$7.00 resulting in net cash proceeds to the Company totaling \$2,890,000.

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.

Assumptions

The fair value of each option award is estimated on the date of grant using a Black-Scholes option valuation model that uses the assumptions noted in the following table. Expected volatilities are based on historical volatility of the Company's stock. The Company uses historical data to estimate option exercise and employee termination behavior. The expected term of options granted is derived from the historical exercise activity over the past 15 years, and represents the period of time that options granted are expected to be outstanding. The Company used the shortcut method to calculate the expected term of its options granted during the first quarter of 2006 that had a four year vesting life as it has no historical experience for the expected term of options with a four-year life. All other options granted with a three year vesting life during the fiscal year ended December 29, 2006 had an expected term of 5.2 years derived from historical exercise and termination activity. The Company has calculated a 10.5% estimated forfeiture rate used in the model for fiscal year 2006 option grants based on historical forfeiture experience. The risk-free rate for periods within the contractual life of the option is based on the U.S. Treasury yield curve in effect at the time of grant.

	Fiscal Year Ended	
	December 29, 2006	December 30, 2005
Expected dividend yield	0%	0%
Expected volatility	73%	70%
Risk-free interest rate	4.17%	4.35%
Expected term (in years)	5.2&7	4.3

A summary of option activity under the Plans as of December 29, 2006, December 30, 2005, and December 31, 2004, and changes during the years then ended are presented below:

Shares	Weighted- Average Exercise	Weighted- Average Remaining Contractual	Aggregate Intrinsic Value
--------	---	--	--

Options	(000 s)	Price	Term	(000 s)
Outstanding at December 30, 2005	3,870	\$ 6.23		
Granted	401	7.35		
Exercised	(753)	3.84		
Forfeited or expired	(46)	4.15		
Outstanding at December 29, 2006	3,472	\$ 5.62	5.6	\$ 5,109
Exercisable at December 29, 2006	2,440	\$ 7.29	4.3	\$ 3,615

F-23

Table of Contents**STAAR SURGICAL COMPANY AND SUBSIDIARIES****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

The weighted-average grant-date fair value of options granted during the fiscal year ended December 29, 2006 was \$4.96. The total fair value of options vested during fiscal year ended December 29, 2006 was \$1,725,000. The total intrinsic value of options exercised during the year ended December 29, 2006 was \$2,038,000.

	Number of Shares	Weighted Average Exercise Price
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 31, 2004	2,535	\$ 7.27
Options exercisable at December 30, 2005	2,728	\$ 6.77

A summary of the status of the Company's non-vested shares as of December 29, 2006 and changes during the period is presented below:

Nonvested Shares	Shares (000 s)	Weighted- Average Grant Date Fair Value
Nonvested at December 30, 2005	1,142	\$ 2.99
Granted	401	4.86
Vested	(484)	1.98
Forfeited	(27)	3.71
Nonvested at December 29, 2006	1,032	\$ 3.30

As of December 29, 2006, there was \$2.2 million of total unrecognized compensation cost related to non-vested share-based compensation arrangements granted under the Plans. That cost is expected to be recognized over a weighted-average period of 1.41 years.

Table of Contents**STAAR SURGICAL COMPANY AND SUBSIDIARIES****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

The following table summarizes information about stock options outstanding and exercisable at December 29, 2006 (in thousands, except per share data):

Range of Exercise Prices	Number Outstanding at 12/29/06	Options Outstanding		Number Exercisable at 12/29/06	Weighted-Average Exercise Price
		Weighted-Average Remaining Contractual Life	Weighted-Average Exercise Price		
\$ 1.70 to \$ 2.15	45	4.7 years	\$ 1.70	45	\$ 1.70
\$ 2.96 to \$ 4.30	1,319	5.6 years	\$ 3.76	896	\$ 3.68
\$ 4.64 to \$ 6.92	616	6.9 years	\$ 6.06	291	\$ 5.65
\$ 7.00 to \$10.19	664	6.9 years	\$ 8.28	380	\$ 8.64
\$10.60 to \$13.63	828	3.8 years	\$ 11.47	828	\$ 11.47
\$ 1.70 to \$13.63	3,472	5.6 years	\$ 5.62	2,440	\$ 7.29

Receivables from Former Directors

As of December 29, 2006 and December 30, 2005, notes receivable (excluding reserves) from a former director totaling \$0 and \$2.0 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 were secured by stock pledge agreements and matured on various dates through July 1, 2006.

During 2006, the Company settled the last of its notes receivable from a former director totaling \$1,961,000 (including accrued interest) for a cash payment of \$175,000 and proceeds from the sale of 120,000 shares of pledged Company stock of \$870,000, which was received on October 3, 2006. The deficiency on the notes was applied against reserves recorded against the notes in 2005 and 2004 and in 2006, \$331,000 of excess reserves was reversed. Amounts are included in the Company's *Consolidated Statement of Operations - Note reserves (reversals)*.

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. Current and long-term obligations under capital leases are classified in other current liabilities and other long-term debt in the Company's Consolidated Balance Sheets.

Estimated future minimum lease payments under leases having initial or remaining non-cancelable lease terms in excess of one year as of December 29, 2006 were approximately as follows (in thousands):

Fiscal Year	Operating Leases	Capital Leases
2007	\$ 1,344	\$ 647
2008	1,199	590
2009	762	418
2010	675	65
2011	274	
Total minimum lease payments	\$ 4,254	\$ 1,720
Less amounts representing interest		(263)
	\$ 4,254	\$ 1,457

F-25

Table of Contents**STAAR SURGICAL COMPANY AND SUBSIDIARIES****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

Rent expense was approximately \$1.2 million for each of the years ended December 29, 2006, December 30, 2005, and December 31, 2004, respectively.

The Company had the following assets under capital lease at December 29, 2006 and December 30, 2005 (in thousands):

	2006	2005
Machinery and equipment	\$ 1,290	\$ 14
Furniture and fixtures	145	
Leasehold improvements	111	
	1,546	14
Less accumulated depreciation and amortization	109	7
	\$ 1,437	\$ 7

Depreciation expense for assets under capital lease for each of the years ended December 29, 2006, December 30, 2005, and December 31, 2004 was approximately \$146,000, \$4,000 and \$4,000, 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 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 2006, 2005, and 2004 were approximately \$502,000, \$728,000, and \$644,000, respectively.

As of December 29, 2006, estimated future annual purchase commitments under this contract are as follows (in thousands):

Fiscal Year

2007	\$ 600
2008	689
	\$ 1,289

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 liability insurance through a third party carrier.

Tax Filings

The Company's tax filings are subject to audit by taxing authorities in jurisdictions where it conducts business. These audits may result in assessments of additional taxes that are subsequently resolved with the authorities or potentially through the courts. Management believes the Company has adequately provided for any ultimate

Table of Contents**STAAR SURGICAL COMPANY AND SUBSIDIARIES****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

amounts that are likely to result from these audits; however, final assessments, if any, could be different than the amounts recorded in the consolidated financial statements.

Employment Agreements

The Company's Chief Executive Officer and certain other officers have as provisions of their employment agreements certain rights, including continuance of cash compensation and benefits, upon a change in control, which may include an acquisition of substantially all of its assets.

Litigation and Claims

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***

Other current liabilities consisted of the following at December 29, 2006 and December 30, 2005 (in thousands):

	2006	2005
Accrued salaries & wages	\$ 1,974	\$ 1,934
Accrued income taxes	830	923
Commissions due to outside sales representatives	800	654
Payable related to acquisition of minority interest in Australia subsidiary	770	
Accrued audit expenses	517	287
Accrued insurance	484	484
Other	2,199	1,527
	\$ 7,574	\$ 5,809

No item in other above exceeds 5% of total other current liabilities.

Note 13 Related Party Transactions

The Company has had significant related party transactions as discussed in Notes 7, 10, 11 and 17.

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 29, 2006 and December 30, 2005 were \$116,000 and \$110,000, 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 29, 2006, December 30, 2005, and December 31, 2004, were \$0, \$2,000, and \$13,000, respectively.

F-27

Table of Contents**STAAR SURGICAL COMPANY AND SUBSIDIARIES****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Note 14 Supplemental Disclosure of Cash Flow Information**

Interest paid was \$175,000, \$181,000 and \$159,000 for the years ended December 29, 2006, December 30, 2005, and December 31, 2004, respectively. Income taxes paid amounted to approximately \$731,000, \$1,047,000 and \$1,602,000 for the years ended December 29, 2006, December 30, 2005, and December 31, 2004, respectively.

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

	2006	2005	2004
Non-cash investing activities:			
Purchase of fixed assets on terms	\$ 1,228	\$ 200	\$
Non-cash financing activities:			
Notes receivable reserve	(331)	746	500
Other charges	331	(746)	(500)
Acquisition of business:			
Minority interest acquired	\$	\$	\$ 203
Goodwill			1,107
Note payable			(542)
Cash paid			(768)

Note 15 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):

	2006	2005	2004
Basic weighted average shares outstanding	25,227	23,704	19,602
Diluted effect of stock options and warrants			
Diluted weighted average shares outstanding	25,227	23,704	19,602

Potential common shares of 2.6 million, 3.9 million, and 3.1 million for the fiscal years ended December 29, 2006, December 30, 2005, and December 31, 2004, respectively, were excluded from the computation as the shares would have had an anti-dilutive effect.

Note 16 Geographic and Product Data

The Company markets and sells its products in approximately 50 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

Table of Contents**STAAR SURGICAL COMPANY AND SUBSIDIARIES****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

customers between those in the United States, Germany, Australia, and other locations for each year, is set forth below (in thousands):

	2006	2005	2004
Sales to unaffiliated customers			
U.S.	\$ 22,293	\$ 18,715	\$ 21,643
Germany	21,135	22,433	22,128
Australia	2,178	2,722	1,914
Other	10,676	7,433	6,000
Total	\$ 56,282	\$ 51,303	\$ 51,685

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

	2006	2005	2004
Cataract	\$ 43,099	\$ 45,361	\$ 46,772
Refractive	12,514	5,288	4,066
Glaucoma	669	654	847
Total	\$ 56,282	\$ 51,303	\$ 51,685

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

	2006	2005
Long-lived assets		
U.S.	\$ 8,153	\$ 8,072
Germany	7,208	6,952
Switzerland	1,140	1,646
Australia	1,318	1,379

Total \$ 17,819 \$ 18,049

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 17 Subsequent Event

On March 21, 2007, the Company executed a promissory note to Broadwood Partners, L.P. (Noteholder), in the amount of \$4.0 million, the proceeds of which may be used for general corporate purposes. The note bears interest at a rate of 10% per annum, payable quarterly, is unsecured, may be prepaid without penalty, and matures on March 21, 2010. The note contains certain affirmative and negative covenants but no financial covenants (other than avoidance of insolvency). The note provides for the issuance of 70,000 warrants upon execution of the note and additional

F-29

Table of Contents**STAAR SURGICAL COMPANY AND SUBSIDIARIES****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

warrants quarterly so long as the note is outstanding. The warrant agreement provides that the Company will register the stock for resale with the SEC. Based on publicly available information filed with the Securities and Exchange Commission (the "SEC"), on the date of the transaction Broadwood Partners L.P. beneficially owned 2,492,788 shares of the Company's common stock, comprising 9.7% of the Company's common stock as of March 21, 2007, and Neal Bradsher, President of Broadwood Partners, L.P., may have been deemed to beneficially own 2,518,688 shares of the Company's common stock, comprising 9.8% of the Company's common stock as of that date.

STAAR's activities as a sponsor of biomedical research are subject to review by the Bioresearch Monitoring Program of the FDA Office of Regulatory Affairs ("BIMO"). On March 14, 2007, BIMO concluded a routine audit of the Company's clinical trial records as a sponsor of biomedical research in connection with the Company's Supplemental Pre-Market Approval application for the Toric ICL ("TICL"). At the conclusion of the audit the Company received eight Inspectional Observations on FDA Form 483 noting noncompliance with regulations. The Company is preparing its response to the Inspectional Observations and expects to address the concerns raised by BIMO through voluntary corrective actions. Most of the observed instances of non-compliance took place during the 2000-2004 period and the Company expects to show that some of these have already been addressed by corrective actions made in response to BIMO's observations of December 11, 2003 in connection with the Company's application for the ICL.

The Company does not believe that the Inspectional Observations affect the integrity of the Toric clinical study. However, the determination of whether the Inspectional Observations affect the use of the Toric clinical study in the Toric application will be at the discretion of the FDA Office of Device Evaluation ("ODE"). Obtaining FDA approval of medical devices is never certain. The Company cannot assure investors that the ODE will grant approval to the TICL, or that the scope of requested TICL approval could not be limited by the FDA or the Ophthalmic Devices Panel.

Note 18 Quarterly Financial Data (Unaudited)

Summary unaudited quarterly financial data from continuing operations for fiscal 2006 and 2005 is as follows (in thousands except per share data):

December 29, 2006	1st Qtr.	2nd Qtr.	3rd Qtr.	4th Qtr.
Revenues	\$ 13,315	\$ 14,561	\$ 13,139	\$ 15,267
Gross profit	6,399	7,040	6,401	6,593
Net loss	(3,362)	(3,218)	(2,789)	(5,675)
Basic and diluted loss per share	(.14)	(.13)	(.11)	(.22)
December 30, 2005	1st Qtr.	2nd Qtr.	3rd Qtr.	4th Qtr.
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)

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.

Significant Fourth Quarter Adjustments

During the fourth quarter of 2006, the Company recorded two significant adjustments. The Company took an obsolescence charge of \$807,000 against certain IOL inventory in anticipation of new product launches that are expected to take place in 2007. The Company will continue to monitor the inventory reserve to ensure that the

Table of Contents

STAAR SURGICAL COMPANY AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

amount is appropriate. In addition to the inventory reserve the Company has reserved \$700,000 for additional taxes in connection with the findings at the Company's German subsidiary. The Company will seek to reduce the amount in discussions with the German Ministry of Finance.

F-31

Table of Contents

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 29, 2007 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 29, 2006, and for each of the three years in the period ended December 29, 2006. 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 29, 2007

F-32

Table of Contents

STAAR SURGICAL COMPANY AND SUBSIDIARIES

SCHEDULE II VALUATION AND QUALIFYING ACCOUNTS AND RESERVES

Column A Description	Column B Balance at Beginning of Year	Column C Additions (In thousands)	Column D Deductions	Column E Balance at End of Year
2006				
Allowance for doubtful accounts and sales returns deducted from accounts receivable in balance sheet	\$ 480	\$ 348	\$ 138	\$ 690
Deferred tax asset valuation allowance	33,662	6,774		40,436
Notes receivable reserve	1,246		1,246	
	\$ 35,388	\$ 7,122	\$ 1,384	\$ 41,126
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
	\$ 29,132	\$ 6,427	\$ 171	\$ 35,388
2004				
Allowance for doubtful accounts and sales returns deducted from accounts receivable in balance sheet	\$ 734	\$ 236	\$ 510	\$ 460
Deferred tax asset valuation allowance	22,075	6,097		28,172
Notes receivable reserve		500		500
	\$ 22,809	\$ 6,833	\$ 510	\$ 29,132