STAAR SURGICAL CO
Form 10-K
March 29, 2007

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

Form 10-K

(Mark One)

þ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 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	**95-3797439**
(State or other jurisdiction of incorporation or organization)	*(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 o No þ

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 o No þ

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

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

Indicate by check mark whether the registrant is 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 o Accelerated filer þ Non-accelerated filer o

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

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.

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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 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 Visian® ICL and Visian™ Toric ICL (TICL) treat refractive disorders such as myopia (near-sightedness), hyperopia (far-sightedness) and astigmatism. These disorders of vision affect a large proportion of the population. Unlike the IOL, which replaces a cataract patient s cloudy lens, these products are designed to work with the patient s natural lens to correct refractive disorders. The surgeon implants the foldable ICL or TICL through a tiny incision, generally under local anesthesia. STAAR began selling the ICL outside the U.S. in 1996 and the TICL in 2002. These products are sold in 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

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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 know 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.

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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^{tm} 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%

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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

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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.

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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

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believe they still provide an opportunity for us as we introduce improvements in silicone IOL technology and build market awareness of our Collamer IOLs and improved injection systems.

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

We believe that the following providers of laser surgical procedures comprise our primary competition in the marketplace for patients seeking surgery to correct refractive conditions: Advanced Medical Optics (AMO), Alcon, Bausch & Lomb, Nidek and Wave Light. All of these companies market Excimer lasers for corneal refractive surgery. Approval of custom ablation, along with the addition of wavefront technology, has increased awareness of corneal refractive surgery by patients and practitioners. Conductive Keratoplasty (CK) by Refractec competes for the hyperopic market for +.75 to +3.0 diopters. In the phakic implant market, there are only two approved phakic IOLs available in the U.S., our Visian™ ICL and the AMO Verisye. 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

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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.

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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

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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

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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 l0-K contains forward-looking statements, which are subject to a variety of risks and uncertainties. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth below.

Risks Related to Our Business

We have a history of losses and anticipate future losses.

We have reported losses in each of the last 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

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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 carryfowards 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

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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

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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

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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

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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

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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.

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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.

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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

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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.

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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.

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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.

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

The following table sets forth selected consolidated financial data with respect to the five most recent fiscal years ended December 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	