STAAR SURGICAL CO
Form 10-K
April 02, 2009

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 January 2, 2009

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, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

o Large accelerated filer þ Accelerated filer o Non-accelerated filer o Smaller reporting company
(Do not check if a smaller reporting company)

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 27, 2008, the last business day of the registrant's most recently completed second fiscal quarter, was approximately $91,708,703 based on the closing price per share of $3.11 of the registrant's Common Stock on that date.

The number of shares outstanding of the registrant's Common Stock as of March 30, 2009 was 30,018,013.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement relating to its 2009 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 any disc 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, manufactures and sells innovative intraocular lenses, or IOLs, implantable Collamer lenses, or ICLs, and other ophthalmic surgical products, used primarily in cataract and refractive surgery. We manufacture products in the U.S., Switzerland and Japan and distribute our products 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®, SonicWAVETM and AquaFlowTM 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.

Intraocular lenses. Most of our revenue is generated by manufacturing and selling foldable intraocular lenses, known as IOLs. A foldable IOL is a prosthetic lens used to replace a cataract patient's natural lens after it has been extracted in minimally invasive small incision cataract surgery. STAAR makes IOLs out of silicone and out of Collamer®, STAAR's proprietary biocompatible collagen copolymer lens material. STAAR's IOLs are available in both three-piece and one-piece designs. Over the years, we have expanded our range of IOLs to include the following:

- The silicone Toric IOL, used in cataract surgery to treat preexisting astigmatism;
- The Preloaded Injector, a three-piece silicone or acrylic IOL preloaded into a single-use disposable injector;
- Aspheric three-piece IOLs, available in silicone or Collamer, designed to provide a clearer image than traditional spherical IOLs, especially in low light.

Implantable Collamer lenses. Manufacturing and selling lenses used in refractive surgery is an increasingly important source of revenue for STAAR. We have used our proprietary biocompatible Collamer material to develop and manufacture implantable Collamer lenses, or ICLs. STAAR's VISIANTM ICL and VISIANTM Toric ICL, or TICLTM, 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 Visian lens through a tiny incision, generally under local anesthesia. STAAR began selling the Visian ICL outside the U.S. in 1996 and inside the U.S. in 2006. STAAR began selling the Visian TICL

outside the U.S. in 2002. These products are sold in more than 45 countries. STAAR's goal is to establish the position of the ICL and TICL throughout the world as one of the primary choices for refractive surgery.

Other Surgical Products. As part of our strategic approach to provide complementary products for use in ophthalmic 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, Cruise Control, a single-use disposable filter which allows for a faster, cleaner phacoemulsification procedure and is compatible with all phacoemulsification equipment, and the AquaFlow Collagen Glaucoma Drainage Device, an implantable device used for the surgical treatment of glaucoma. We also sell other related instruments, devices, surgical packs and equipment that we manufacture or that are manufactured by others.

Distribution. STAAR's wholly owned subsidiary, Domilens Vertrieb fuer medizinische Produkte GmbH ("Domilens") is a leading distributor of ophthalmic products in Germany. Products sold by Domilens include implantable lenses, related surgical equipment, consumables and other supplies. Domilens sells custom surgical kits that incorporate a surgeon's preferred supplies and consumables in a single ready-to-use package, and services phacoemulsification and other surgical equipment. In addition to distributing and servicing products of third party manufacturers, Domilens distributes STAAR's ICLs, IOLs, and Preloaded Injectors.

Operations

STAAR has significant operations both within and outside the U.S. Revenue from activities outside the U.S. accounted for 75% of our total revenues in fiscal year 2008. STAAR's principal business units and their operations are as follows:

- United States. STAAR operates its global administrative headquarters and a manufacturing facility in Monrovia, California. The Monrovia manufacturing facility principally makes Collamer and silicone IOLs and injector systems for IOLs and ICLs. STAAR also manufactures the Collamer material in the U.S.

- Switzerland. STAAR operates an administrative and manufacturing facility in Nidau, Switzerland under its wholly owned subsidiary, STAAR Surgical AG. The Nidau manufacturing facility makes all of STAAR's ICLs and TICLs and also manufactures Collamer IOLs and the AquaFlow Device. STAAR Surgical AG handles distribution and other administrative affairs for Europe and other territories outside North America and Japan.

- Japan. At the beginning of fiscal year 2008, STAAR completed the acquisition of the remaining 50% interest in its joint venture Canon Staar, Co., following which the entity's name was changed to STAAR Japan, Inc. ("STAAR Japan"). STAAR Japan operates an administrative facility in Shin-Urayasu, Japan and a manufacturing facility in Ichikawa City. All of STAAR's preloaded injectors are manufactured at the Ichikawa City facility. STAAR Japan is also currently seeking approval from the Japanese regulatory authorities to market in Japan STAAR's Visian ICL and TICL, Collamer IOL and AquaFlow Device.

- Germany. Domilens, a wholly owned subsidiary of STAAR Surgical AG, operates its distribution business at facilities in Hamburg, Germany.

The global nature of STAAR's business operations subjects it to risks, including the effect of changes in currency exchange rates, differences in laws, including laws protecting intellectual property and regulating medical devices, political risks and the challenge of managing foreign subsidiaries. See " Item 1A. Risk Factors — The global nature of our business may result in fluctuations and declines in our sales and profits" and " — The success of our international operations depends on our successfully managing our foreign subsidiaries."

The Human Eye

The following discussion provides background information on the structure, function and some of the disorders of the human eye to enhance the reader's understanding of our products described in this report. The human eye is a specialized sensory organ capable of receiving visual images and transmitting them to the visual center in the brain. Among the main parts of the eye are the cornea, the iris, the lens, the retina, and the trabecular meshwork. The cornea is the clear window in the front of the eye through which light first passes. The iris is a muscular curtain located behind the cornea which opens and closes to regulate the amount of light entering the eye through the pupil, an opening at the center of the iris. The lens is a clear structure located behind the iris that changes shape to focus light to the retina, located in the back of the eye. The retina is a layer of nerve tissue consisting of millions of light receptors called rods and cones, which receive the light image and transmit it to the brain via the optic nerve. The posterior

chamber of the eye, located behind the iris and in front of the natural lens, is filled with a watery fluid called the aqueous humor, while the portion of the eye behind the lens is filled with a jelly-like material called the vitreous humor. The trabecular meshwork, a drainage channel located between the iris and the surrounding white portion of the eye, maintains a normal pressure in the anterior chamber of the eye by draining excess aqueous humor.

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

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

History of STAAR

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 approximately 50 countries and has been implanted in more than 125,000 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.

- In 2001, STAAR commenced commercial sales of its Visian Toric ICL or 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. Other significant markets for the TICL include China, Korea, and Canada. The TICL is not yet approved for commercial sale in the U.S.

- In late 2003, STAAR Japan introduced the first preloaded IOL 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, and to date only, small incision phakic implant commercially available in the United States.

Financial Information about Segments and Geographic Areas

STAAR's principal products are IOLs, ICLs, and other complementary products used in ophthalmic surgery. Because 100% of STAAR's sales are generated from the ophthalmic surgical product segment, the Company operates as one operating segment for financial reporting purposes. See Note 19 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.

Minimally Invasive Intraocular Lenses (IOLs). 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 less than 3mm in length, and for one model as small as 2.2 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.

The addition of aspheric optics to STAAR's IOL designs has been a primary focus of STAAR's recent development efforts. Aspheric IOLs use advanced optical designs intended to provide a clearer image than traditional spherical lenses, especially in low light, which has led to significant market share gains for aspheric designs. STAAR introduced its first aspheric IOLs made of silicone and Collamer in 2007 and received New Technology IOL "NTIOL" designation for both products in 2008 which qualify them for additional reimbursement.

STAAR Japan introduced the first Preloaded Injector in international markets in late 2003. The Preloaded Injector is a silicone or acrylic IOL packaged and shipped in a pre-sterilized, disposable injector ready for use in cataract surgery. We believe the Preloaded Injector offers surgeons improved convenience and reliability. In 2006 STAAR Japan began selling in Japan an acrylic-lens-based Preloaded Injector employing a lens supplied by Nidek Inc., a Japanese ophthalmic company. Nidek also assembles and sells in Japan the acrylic Preloaded Injector under its own brand, using injector parts purchased from STAAR Japan. STAAR Japan's agreement with Nidek provides for the sale of the acrylic Preloaded Injector in additional territories by mutual agreement of the two companies. The Preloaded Injector is not yet available for sale in the U.S.

We have developed and currently market, principally in the U.S., 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.

Sales of IOLs accounted for approximately 44% of our total revenues for the 2008 fiscal year, 39% of total revenues for the 2007 fiscal year and 45% of total revenues for the 2006 fiscal year.

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 those used to implant 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 usually occurs 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, China, Canada, Korea and Singapore. Applications are pending in Australia and Japan, 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 (see “Regulatory Matters – Recent Correspondence with FDA Regarding Clinical Oversight and TICL Approval”).

The Hyperopic ICL is approved for use in countries that require the European Union CE Mark and in China and Canada.

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 often made to order.

Sales of ICLs (including TICLs) accounted for approximately 25% of our total revenues for the 2008 fiscal year, 26% in 2007 fiscal year and 21% of total revenues for the 2006 fiscal year.

Other Surgical Products

As part of our strategic approach to provide complementary products for use in ophthalmic 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, Cruise Control, a single-use disposable filter which allows for a faster, cleaner phacoemulsification procedure and is compatible with all phacoemulsification equipment, and the AquaFlow Collagen Glaucoma Drainage Device, an implantable device used for the surgical treatment of glaucoma. We also sell other related instruments, devices, surgical packs and equipment that we manufacture or that are manufactured by others.

Sales of other surgical products accounted for approximately 31% of our total revenues for the 2008 fiscal year, 35% of total revenues for the 2007 fiscal year and 33% of total revenues for the 2006 fiscal year.

German Distribution Business

Domilens, STAAR's German subsidiary, is an ophthalmic distribution company. Domilens principally resells and services products manufactured by third parties, along with STAAR's refractive products and Preloaded Injectors. Substantially all of Domilens' revenues are generated from the ophthalmic surgical products market. Domilens reported sales of $25.1 million in fiscal year 2008, $23.7 million in fiscal year 2007 and $21.1 million in fiscal year 2006.

Domilens sells IOLs and other ophthalmic devices, sells and services phacoemulsification systems and other surgical equipment, and sells instruments, supplies and disposables. A significant part of Domilens business is the assembly of custom surgical kits that package a surgeon's preferred supplies and disposables in convenient form for a single surgery. Domilens sells many of its third party products under its own private label.

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 January 2, 2009, we owned approximately 242 United States and foreign patents and had approximately 94 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 and to manufacture the collagen copolymer lens material. In developing its proprietary biocompatible Collamer material STAAR developed and patented additional technology. STAAR has also enhanced the originally licensed ICL design through patented features designed to make it safer and more effective. 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 AquaFlow Device, our phacoemulsification system, our insertion devices, and other technologies of the Company.

Our patent portfolio includes a significant group of patents granted or pending in the U.S. and other countries and in Japan, that we acquired in connection with the purchase of the remaining 50% interests in STAAR Japan in early fiscal 2008. These include numerous patents covering our Preloaded Injector technology. Prior to our acquisition, STAAR Japan held exclusive rights to these patents. STAAR believes that STAAR Japan’s patents enable it to better capitalize on the competitive advantage of our Preloaded Injector technology outside of Japan.

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 patent proprietary elements 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 may result in the loss of market exclusivity, we may continue to derive commercial benefits from these products. Also, we may continue to enjoy market exclusivity if we have maintained trade secrecy over the use of proprietary technology or if medical device regulations require our competitors to conduct clinical research or otherwise satisfy requirements before they can use the technology. 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.

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 dependent upon a single or a few customers.

We distribute products directly to the physician or facility in the United States, Germany, and Australia, and rely primarily on local distributors in other countries. In Japan we both sell directly and through a local distributor. Where we distribute products directly, we rely on local sales representatives to help generate sales by promoting and demonstrating our products with physicians. In Germany, Japan and Australia, sales representatives are primarily employed directly by us. In the U.S., we rely on both directly employed representatives and independent sales representatives to sell our products under the supervision of directly employed sales managers.

Our internal marketing department develops the strategies to be employed by our agents, employees and distributors through the activities of our internal marketing department. The marketing department supports selling efforts by developing and providing 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, include Alcon Laboratories ("Alcon"); Abbott Medical Optics, previously known as Advanced Medical Optics ("AMO"); and Bausch & Lomb. According to a 2008 Market Scope report, Alcon holds 57% of the U.S. IOL market, followed by AMO with 23% and Bausch & Lomb with 15%. 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, which is considered an advanced material. Acrylic IOLs currently account for a 76% 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. As part of our effort to increase market uptake of our Collamer IOLs, we introduced an aspheric three-piece Collamer IOL in November 2007 and introduced

the nanoPOINT™ injector, which delivers STAAR's single piece Collamer IOL through a 2.2 mm incision. In 2009 STAAR expects to introduce an aspheric version of its single-piece Collamer lens, which will also be deliverable through the nanoPOINT injector, and an advanced injector system for the three-piece Collamer lens.

The addition of aspheric optics to STAAR's IOL designs has been a primary focus of STAAR's recent development efforts. Aspheric IOLs use advanced optical designs intended to provide a clearer image than traditional spherical lenses, especially in low light, which has led to significant market share gains for aspheric designs. In recognition of these advantages the Centers for Medicare and Medicaid Services ("CMS") grants New Technology IOL ("NTIOL") status to aspheric IOLs that can demonstrate improved visual performance over conventional IOLs, allowing an extra $50 reimbursement per lens implanted in an ASC (ambulatory surgical center). All of STAAR's aspheric lenses feature a proprietary optical design (patent pending) that is optimized for the naturally curved surface of the retina and certain other anatomical features of the human eye, and provides outstanding image quality even if decentered. Because the overwhelming majority of IOL purchases in the U.S. are implanted at ASCs and reimbursed through Medicare, NTIOL status significantly increases STAAR's potential margin on qualifying lenses. During 2008 CMS granted NTIOL status to STAAR's single-piece and three-piece aspheric Collamer IOLs, and to its three-piece silicone aspheric IOL. STAAR believes it is the first company to be granted three NTIOL designations.

Although the market for silicone IOLs, which currently account for 20% of the U.S. IOL market, has declined in recent years, we believe they still provide an opportunity for us as we continue to introduce improvements to the silicone IOL technology and build awareness of our Collamer IOLs and improved injection systems. In particular, we believe that our recently introduced aspheric silicone three-piece lens and the expected 2009 introduction of preloaded injectors to deliver this lens will enhance STAAR's ability to maintain market share within the silicone market sector.

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 vision correction. In particular, eyeglasses and external contact lenses are much cheaper in the short term 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: AMO, Alcon, Bausch & Lomb, and Nidek. All of these companies market Excimer lasers for corneal refractive surgery. Approval of custom laser ablation, along with the addition of wavefront technology, has increased awareness of corneal refractive surgery by patients and practitioners. In the phakic implant market, there are only two approved phakic IOLs available in the U.S., our Visian TM ICL and the AMO Verisyse. In international markets, our ICL's main competition is the AMO Verisyse, which is also sold as 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 (the "Act"), the FDA has the authority to adopt, and has adopted, 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 approval,
- require 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, associated adverse events, and certain recalls or field actions to the FDA, and

- prohibit the export of devices that do not comply with the Act unless they comply with specified requirements, including but not limited to requirements that exported devices comply with applicable foreign regulations, do not conflict with foreign laws, and that the export not be contrary to public health in the U.S. or the importing country.

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 establishment registration and device listing with FDA, labeling and record-keeping requirements), Class II (performance standards in addition to general controls) or Class III (pre-market approval ("PMA") required before commercial marketing). Class III devices are the most extensively regulated because the FDA has determined they are life-supporting, are of substantial importance in preventing impairment of health, or present a potential unreasonable risk of illness or injury. The effect of assigning a device to Class III is to require each manufacturer to submit to the FDA a PMA that includes information on the safety and effectiveness of the device.

A medical device that is substantially equivalent to a directly related medical device previously in commerce may be eligible for the FDA's pre-market notification "510(k) review" process. FDA 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 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 lens injectors.

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 Division of Bioresearch Monitoring ("BIMO") of the Office of Compliance in FDA's Center for Devices and Radiological Health.

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.

The member countries of the European 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 European Directives and associated guidelines concerning manufacturing and quality control, technical specifications and biological or chemical and clinical safety. We have obtained the CE Mark for all of our principal products including our ICL and TICL, IOLs (excluding IOL's with aspheric optics), injectors and our AquaFlow Device.

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FDA Review of STAAR's Quality Systems

The FDA's most recent general quality inspections of STAAR's facilities were a regularly scheduled inspection of the Monrovia, California facility, between February 23 and March 4, 2009, a post-market inspection of the Aliso Viejo, California facility on August 7, 2006, and a post-market inspection of the Nidau, Switzerland facility between September 26 and September 28, 2006. The recent inspection of the Monrovia, California facility that concluded on March 4, 2009 resulted in the issuance of three observations by the investigators of nonconformity on Form FDA-483. STAAR has agreed with the observations and has completed and/or is implementing corrective actions to address each observation. We have prepared a comprehensive response to the investigators' observations that we believe appropriately addresses each of the issues raised on the Form FDA-483. The post-market inspections of Aliso Viejo, California and Nidau Switzerland resulted in no observations of noncompliance. Based in part on these inspections and the FDA inspections conducted in 2005, STAAR believes that it is substantially in compliance with the FDA's Quality System Regulations and Medical Device Reporting regulations.

STAAR's ability to continue its U.S. business depends on the continuous improvement of its quality systems and its ability to demonstrate compliance with FDA regulations. Accordingly, for the foreseeable future STAAR's management expects its strategy to include devoting significant resources and attention to those efforts.

Status of TICL Submission

STAAR's activities as a sponsor of biomedical research are subject to review by the FDA. BIMO inspections are part of a program designed to ensure that data and information contained in requests for Investigational Device Exemptions (IDE), Premarket Approval (PMA) applications, and Premarket Notification submissions (510k) are scientifically valid and accurate. Another objective of the program is to ensure that human subjects are protected from undue hazard or risk during the course of scientific investigations. While the past procedural violations noted in the Warning Letter are serious in nature and required comprehensive corrective and preventative actions, the Company does not believe that these nonconformities undermine the scientific validity and accuracy of its clinical data, or that human subjects were subjected to undue hazard or risk.

Following STAAR's submission of a Pre-Market Approval application (PMA) supplement for the TICL to the FDA on April 28, 2006, FDA's BIMO conducted an inspection of STAAR's clinical study procedures, practices, and documentation related to the TICL between February 15 and March 14, 2007. At the close of the inspection, STAAR received eight inspectional observations on Form 483, to which it responded on April 5, 2007. Notwithstanding the response, on June 26, 2007 the FDA's BIMO branch issued a Warning Letter to STAAR noting four areas of noncompliance observed during the BIMO inspection. STAAR provided its written response to the Warning Letter to the FDA on July 31, 2007.

On August 3, 2007 STAAR received a letter from the FDA Office of Device Evaluation ("ODE") notifying STAAR that the review of the TICL application would be placed on integrity hold (i.e., halted) until STAAR completes specified actions establishing the integrity and reliability of the clinical data under the TICL application and the robustness of STAAR's clinical trial procedures and systems. Noting the same deficiencies cited in the June 26, 2007 Warning Letter from BIMO, and other deficiencies noted in an audit of a clinical study site, ODE requested that STAAR engage an independent third party auditor to conduct an audit of patient records along with a clinical systems audit to ensure accuracy and completeness of data before resubmitting the application.

STAAR's independent third party auditor has completed its audits, has reviewed and certified the amended clinical data that is the source for the data to be included in the resubmission of the TICL application, and has completed its audit report on STAAR's quality systems related to clinical oversight. The third party auditor has submitted its findings directly to the FDA for its examination. The submission of findings from the third party auditor to FDA was in two

audit reports, dated October 8, 2008 and December 15, 2008. The FDA considers the October 8, 2008 report to be complete and has allowed the third party auditor to release it to STAAR. In December 2008, the FDA allowed the third party auditor to release a draft version of the December 15, 2008 report to STAAR. In mid February 2009 the FDA presented the third party auditor with two questions related to the information in the December 15, 2008 report and the third party auditor responded to the questions on or about March 16, 2009. Upon final release of the December 15, 2008 third party audit report to STAAR, STAAR will prepare a corrective action plan that addresses the findings of the third party auditor as reported to FDA. STAAR has reviewed the corrective action plans developed in response to the Warning Letter and the audit findings that the FDA has allowed the third party auditor to release to date and will ensure that the corrective action plan developed to address the independent third party auditor's findings is fully aligned with all of the auditor's findings. If the FDA agrees with the corrective action plan, then an inspection by the local office will be scheduled. If the results of the inspection are satisfactory to FDA, the inspector will forward a report to FDA headquarters and it is expected that the FDA would then lift the integrity hold. After the hold is lifted, STAAR will be permitted to resubmit the clinical data for the TICL application, as certified by the third party auditor, and FDA will resume substantive review of the TICL data. STAAR cannot assure investors that its corrective actions will be satisfactory to FDA, that ODE will grant approval to the TICL, or that the scope of requested TICL approval, if granted, would not be limited by the FDA.

Acquisition of Remaining Interests in Japanese Joint Venture

Early in fiscal year 2008 STAAR completed the acquisition of the remaining interests in its Japan-based joint venture, Canon Staar Co., Inc. ("Canon Staar"), which manufactures the Preloaded Injector. Canon, Inc. and its affiliated marketing company, Canon Marketing Japan Inc. ("CMJ") collectively owned 50% of Canon Staar prior to the closing of the acquisition on December 29, 2007, and STAAR owned the other 50%. Following the acquisition, Canon Staar became a wholly owned subsidiary of STAAR and changed its name to "STAAR Japan, Inc."

Total consideration STAAR paid to Canon Inc. and CMJ (collectively referred to as the "Canon companies" in this Report) consisted of $4 million in cash and the issuance of 1.7 million shares of Series A Redeemable, Convertible Preferred Stock ("Preferred Stock"). STAAR received in return all of the Canon companies' shares of Canon Staar. Each share of the Preferred Stock issued to the Canon companies is convertible for five years at the option of the holder into one share of STAAR's common stock, and will automatically convert after five years into one share of STAAR's common stock. The holders of the Preferred Stock may redeem their shares at their option at a price of $4.00 per share (plus accrued or declared but unpaid dividends) ("Redemption Price") on the occurrence of a change in control or liquidation of STAAR or at any time after the third anniversary of the issuance date. STAAR can call the Preferred Stock at the redemption price after the first anniversary of the issuance date.

Canon Staar, renamed STAAR Japan, was created in 1988 pursuant to a Joint Venture Agreement between STAAR and the Canon companies for the principal purpose of designing, manufacturing, and selling in Japan intraocular lenses and other ophthalmic products. STAAR Japan recorded worldwide sales of $12.7 million in fiscal year 2008. In addition to the business of manufacturing the Preloaded Injector, STAAR Japan is also seeking approval from the Japanese regulatory authorities to market in Japan STAAR's Visian ICL and TICL, Collamer IOL and AquaFlow Device. Prior to December 29, 2007, STAAR has reported its interest in the joint venture under the equity method and did not consolidate Canon Staar's income, cash flow or balance sheet data with STAAR. STAAR Japan's results have been consolidated into STAAR financial statements beginning with the first fiscal quarter of 2008.

The general manager of Canon Staar for most of its history, Isamu Kamijo, agreed to continue serving in this capacity and joined STAAR Japan, Inc. as its President after the closing. He had previously been an employee of Canon Marketing Japan serving at Canon Staar under a secondment arrangement.

Under the agreements governing the joint venture, CMJ had been the exclusive distributor of Canon Staar products in Japan. At the closing STAAR Japan assumed CMJ's IOL distribution business and purchased the remaining inventory of Canon Staar products held by CMJ. Customers list and consignment inventories were transferred to STAAR Japan and the sales staff employed by CMJ in its IOL distribution business had been seconded to STAAR Japan for a period of one year. As of December 31, 2008 this secondment agreement expired and the sales staff covered under this agreement returned to CMJ.

As a result of the acquisition, STAAR acquired a portfolio of 33 patents filed in Japan, the U.S. and elsewhere in the world. These patents, which include claims related to the Preloaded Injector, had previously been held exclusively by the joint venture.

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 also includes clinical activities and regulatory affairs and is comprised of 53 employees. In order to achieve our business objectives, we will continue the investment in research and development.

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During 2008, research and development at STAAR resulted in the grant of NTIOL status for the aspheric three-piece Collamer IOL in March, 2008; and the grant of NTIOL status for the aspheric single-piece Collamer IOL and the aspheric three-piece silicone IOL in July, 2008. The single-piece Aspheric Collamer IOL, which can be delivered through the NanoPOINT injector, is expected to be introduced the first half of 2009. In 2008 STAAR also completed development of an advanced injector system for the three-piece Collamer IOL, which is expected to be introduced in 2009 as well.

STAAR Japan's research and development department has been a leader in injector technology, enabling that company to introduce the first Preloaded Injector to international markets in late 2003. Since STAAR completed its acquisition of the remaining 50% interest in STAAR Japan in early fiscal year 2008, STAAR has incorporated the efforts of STAAR Japan's research and development staff into its global research and development strategy, which is expected to accelerate STAAR's efforts to improve its injector technology and bring preloaded technology to more markets.

During 2009 we expect to continue our focus on research and development in the following areas:

- Development of a Collamer Toric IOL to complement our pioneering silicone Toric IOL;
- Introduction of the "Epiphany" injector system for the three piece Collamer IOL;
- Shelf life studies to expand the shelf life for Collamer IOLs and ICLs;
- FDA approval for the nanoPoint system to deliver the ICL products through a smaller incision;
- Introduction to the U.S. of preloaded injectors to deliver our aspheric, square-edged three-piece silicone IOL.

Also during 2009 we plan to explore the accommodating effects of the Collamer single piece IOL. Many surgeons have reported that their patients receiving the Collamer single piece IOL have better near vision than patients implanted with competitive IOLs. We have established the Collamer Accommodating Study Team (CAST) made up of nine surgeons in the United States to study the range of accommodation in their patients which have received a Collamer single piece IOL. This will be valuable information for users of the current product and will aid in design advancements for the platform.

Research and development expenses were approximately $7,938,000, $6,711,000, and $7,080,000 for our 2008, 2007 and 2006 fiscal years, respectively. STAAR expects to invest approximately 7-10% of sales for research and development in 2009.

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.

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Significant Subsidiaries

As of April 1, 2009, the Company's principal and wholly owned subsidiaries were STAAR Surgical AG, STAAR Japan, Inc. and Domilens Vertrieb fuer medizinische Produkte GmbH (a subsidiary of STAAR Surgical AG). The activities of each are described above.

Employees

As of April 1, 2009, we employed approximately 386 persons.

Code of Ethics

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

Additional Information

We make 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 100 F Street, NE, Washington, DC 20549. The public may obtain information about the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC also maintains an Internet site that contains reports, proxy and information statements, and other information regarding the Company and other issuers that file electronically with the SEC at http://www.sec.gov.

Item 1A. Risk Factors

Our short and long-term success is subject to many factors that are beyond our control. Investors and prospective investors should consider carefully the following risk factors, in addition to other information contained in this report. This Annual Report on Form 10-K contains forward-looking statements, which are subject to a variety of risks and uncertainties. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth below.

Risks Related to Our Business

We have a history of losses.

We have reported losses in each of the last several fiscal years and have an accumulated deficit of $125.9 million as of January 2, 2009. Although the Company expects to achieve positive net earnings in 2009, STAAR's history of losses reflects a number of challenges that the Company must continue to overcome and there can be no assurance that it will be successful in doing so. Among the risks and uncertainties are those described in this "Risk Factors" section.

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

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 sales our existing stockholders could experience substantial dilution. An inability to secure additional financing could jeopardize our ability to continue operations.

The report of our Independent Registered Public Accounting Firm contains an explanatory paragraph expressing substantial doubt about our ability to continue as a "going concern."

Because of our limited capital resources and the $4.9 million judgment entered against the Company in March 2009, coupled with a history of losses and negative cash flows, our independent registered public accounting firm has modified its opinion on our financial statements for fiscal year 2008 with a statement that substantial doubt exists regarding STAAR's ability to continue as a "going concern." While STAAR's use of cash has declined in recent periods, and the company believes it is close to generating sufficient cash from sales to support its operations, its current cash resources are not sufficient to satisfy the March 2009 court judgment or to provide reserves against other contingencies that might arise in the next twelve months, especially if the global recession causes sales to fall below projected levels.

Substantial doubt about STAAR's ability to continue as a going concern could affect our relationships with suppliers or customers. In accordance with Generally Accepted Accounting Principles in the U.S., STAAR's balance sheet generally states the book value of STAAR's assets, which does not necessarily represent the value that could be realized from the assets if STAAR could not continue as a going concern.

We are subject to a $4.9 million judgment and face additional litigation.

On March 23, 2009, a California court entered judgment against STAAR for approximately $2.2 million in compensatory damages and $2.7 million in punitive damages in Parallax Medical Systems, Inc. v. STAAR Surgical Company, a case alleging that STAAR willfully and negligently interfered with the prospective business of a former regional manufacturer's representative. While STAAR intends to vigorously contest this outcome through post-trial proceedings and, if necessary, appeal the cost of satisfying the judgment or posting a bond for appeal exceeds STAAR's current capital resources. The court has stayed the execution of judgment and collection of damages until after the completion of post-trial motions and the deadline to file notice of appeal, which is a period of approximately three months. If STAAR is unable to obtain additional capital to satisfy the judgment or post an appeal bond before the expiration of the stay, STAAR could be required to petition for protection under federal bankruptcy laws, which could further impair its financial position and liquidity, and would likely result in a default of its other debt obligations.

Another lawsuit similar to the Parallax case, Moody v. STAAR Surgical Company, is currently scheduled for trial in the Superior Court of California, County of Orange, on May 25, 2009. STAAR believes that the evidence to be presented in Moody does not support liability for intentional or negligent interference, and some facts differ in the two cases. However, the allegedly improper conduct of STAAR is the same in the two cases and Moody will also be tried before a jury. Moody is also seeking punitive damages. Accordingly, the risk that a jury could render a verdict in Moody in a range similar to or greater than the Parallax judgment cannot be eliminated. An adverse judgment in the Moody case would further reduce STAAR's liquidity and capital resources. See "Item 3: Legal Proceedings."

Future legal costs may be material.

In recent periods, STAAR has incurred increased expenses for legal fees, in particular fees related to the defense of the lawsuits by former regional manufacturers' representatives and STAAR's related cross-complaints that are described under "Item 3: Legal Proceedings." While STAAR maintains insurance coverage for a number of litigation risks, including the cost of defending product liability claims, such insurance does not cover those lawsuits or some other types of commercial disputes. The defense of litigation, including fees of external legal counsel, expert witnesses and related costs, is expensive and may be difficult to project accurately. In general, such costs are unrecoverable even if STAAR ultimately prevails in litigation, and could represent a significant portion of STAAR's limited capital resources. To defend lawsuits, STAAR also finds it necessary to divert officers and other employees from their normal business functions to gather evidence, give testimony and otherwise support litigation efforts. STAAR expects to experience higher than normal litigation costs until the lawsuits by former regional manufacturer's representatives are decided, which could include the need to appeal and defend a new trial.

STAAR may also in the future find it necessary to file lawsuits to recover damages or protect its interests. The cost of such litigation could also be significant and unrecoverable, which may also deter STAAR from aggressively pursuing even legitimate claims.

Default under the Senior Promissory Note could result in an acceleration of our indebtedness or increased interest costs or both.

Among the events of default in the Senior Promissory Note ("the Note") held by Broadwood Partners, L.P. is any judgment in excess of $500,000 against the Company that "shall remain unpaid." Because STAAR is not required to pay the Parallax judgment until the expiration of the stay 40 days after final judgment, and because the amount to be paid pursuant to the judgment will not be fixed until final judgment is rendered on or before May 22, 2009, STAAR believes that as of the date of this Report the Parallax judgment should not be deemed "unpaid" and that an event of default under the Senior Promissory Note would not have occurred. To avoid dispute over this matter and to secure the lender's temporary waiver of remedies for an event of default during the stay of the Parallax judgment, STAAR and Broadwood entered into a Temporary Waiver Agreement on April 2, 2009.

Under the Temporary Waiver Agreement, if, prior to the expiration of the stay, STAAR does not satisfy the Parallax judgment or secure an additional stay pending appeal, an event of default will occur under the Note. The event of default would cause an increase of the interest rate from 7% to a maximum of 20% and, if the holder delivers written notice of default, the entire $5 million principal amount and accrued interest of the note will become immediately due and payable. The Temporary Waiver Agreement also provides that if STAAR secures a further stay of judgment pending appeal, but does not satisfy the judgment before the expiration of the original stay period, the Note will not become immediately due and payable but the increased default interest rate will apply unless and until the Parallax judgment is satisfied an all other pending and undecided material litigation is resolved. If applicable, the increased interest rate will result in a $650,000 per year increase in interest on the Note. An event of default under the Note leading to either the increased rate of interest or to the Note becoming immediately due and payable will harm STAAR's financial condition and results of operations.

We may have limited ability to fully use our recorded tax loss carryforwards.

We have accumulated approximately $119.5 million of tax loss carryforwards as of January 2, 2009 to be used in future periods if we become profitable. If we were to experience a significant change in ownership, Internal Revenue Code Section 382 may restrict the future utilization of these tax loss carryforwards even if we become profitable and these tax loss carryforwards will begin to expire between 2020 and 2028.

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 and other FDA regulations. The FDA also regularly inspects for compliance with regulations governing clinical investigations.

Based on the results of the FDA inspections of STAAR's Monrovia, California facilities in 2005, 2006 and 2009, 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.

On June 26, 2007 STAAR received a Warning Letter from the FDA citing four areas of noncompliance noted by the FDA's Bioresearch Monitoring branch during its inspection of STAAR's clinical study procedures, practices, and documentation related to the TICL. The Office of Device Evaluation cited the same deficiencies in a letter placing an integrity hold on the TICL application. While BIMO's oversight covers clinical research, rather than the manufacturing, quality and device reporting issues that have been STAAR's greatest focus in its recent compliance initiatives, STAAR believes that the negative publicity from the BIMO observations and Warning Letter has made it more difficult for STAAR to overcome the harm to its reputation resulting from past FDA proceedings.

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 be successful. 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."

FDA Approval of the Toric ICL, which could have a significant U.S. market, has been significantly delayed.

Part of STAAR's strategy to increase U.S. sales of refractive products has been a plan to introduce the Toric ICL, or TICL, a variant of the ICL that corrects both astigmatism and myopia in a single lens and that is currently marketed outside the U.S. STAAR believes the TICL also has a significant potential market in the U.S. and could accelerate growth of the overall refractive product line. STAAR submitted a supplemental premarket approval application (PMA) for the TICL in April 2006. In August 2007 the FDA placed an integrity hold on the PMA and suspended its consideration of the PMA until STAAR completes specified actions to satisfy FDA concerns regarding deficiencies in

STAAR's oversight of past clinical activities. The actions include engaging an independent third party auditor to conduct a 100% data audit of patient records along with a clinical systems audit to ensure accuracy and completeness of data before submitting amendments to the application for the FDA's review. After resubmission of the application, approval of the TICL will remains in the discretion of the FDA. Neither the approval, nor its timing, is certain. If STAAR is required to conduct additional clinical studies to secure approval of the TICL, significant further delays and costs would likely result.

Global recession could reduce sales of our refractive products.

The global economy is currently in recession. Since at least mid-2008 consumer spending has decreased in the U.S. as credit has become less available, unemployment has increased, and consumer confidence has declined.

Refractive surgery is an elective procedure generally not covered by health insurance. Patients must pay for the procedure, frequently through installment financing arrangements. They can defer the choice to have refractive surgery if they lack the disposable income to pay for it or do not feel their income is secure in the current economic climate. Laser refractive surgery has experienced a significant decrease in demand in the U.S. beginning in the second quarter of 2008. Visian ICL sales have not been as badly affected and generally increased during the 2008 fiscal year; however during the fourth fiscal quarter of 2008 U.S. ICL sales were flat and international Visian ICL and TICL sales declined slightly as compared to the same period as prior year. If the global recession becomes more severe or continues for a protracted period, Visian ICL sales could continue to grow slowly or decline. Because the Visian ICL is STAAR's fastest growing and highest margin product, restricted growth or a decline in its sales could materially harm STAAR's business.

Because cataracts generally affect the elderly, most sales of IOLs and other products used in cataract surgery are reimbursed by government entities worldwide. Accordingly, these sales are generally unaffected by economic downturns or recessions. However, if the global recession becomes more severe or continues for a protracted period, STAAR's customers could slow their payments or delay, reduce or forgo inventory purchases. If STAAR's customers face financial difficulty, they could further slow or default in payment, increasing our collection risk.

Negative publicity concerning complications of laser eye surgery could reduce the demand for our refractive products as well.

Negative publicity about laser eye surgery has recently appeared in the U.S. and some other refractive surgery markets. For example, on April 25, 2008, the FDA Ophthalmic Devices Panel held a public meeting to discuss reports of medical complications and customer satisfaction following refractive surgery. The resulting publicity broadened public awareness of the potential complications of refractive surgery and potential patient dissatisfaction, in particular as a result of LASIK and other corneal laser-based procedures. These concerns may have been a factor in the steep decline in demand for such procedures during 2008. Concerns about complications of refractive laser eye surgery could encourage more patients and doctors to select the Visian ICL as an alternative, but could also decrease patient interest in all refractive surgery, including Visian ICL. Depending on the nature and severity of future negative publicity about refractive surgery, the growth of ICL sales in the U.S. could be limited or sales could decline as a result. Because nearly all candidates for refractive surgery can achieve acceptable vision through the use of spectacles or contact lenses, for most patients the decision to have refractive surgery is a lifestyle choice that depends on high confidence in achieving a satisfactory outcome.

Our core domestic IOL business has suffered declining sales.

The foldable silicone IOL was once 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 taken an increasing 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 competitors also introduced IOLs with advanced aspheric optics earlier than STAAR. During fiscal year 2008 STAAR's U.S. cataract sales declined 9% over the comparable period of the prior year. Our newer line of IOLs made of our proprietary biocompatible Collamer material, and our newly introduced aspheric lenses, while intended to

reverse the trend of declining domestic cataract product sales, may not permit us to recover the market share lost over the last several years.

We have restructured our U.S. sales force but the changes may not reverse the decline in our U.S. sales of cataract products.

From 2007 through early 2009 STAAR comprehensively reorganized its U.S. sales force. STAAR intends these changes to provide greater efficiency and better coordination of its sales efforts as it seeks to reverse the long-term decline in U.S. IOL sales by promoting its new lens designs and delivery systems. In the fourth quarter of 2008 STAAR significantly reduced the rate of decline in its U.S. IOL sales, but has not yet seen an increase in these sales. If our restructured sales force does not perform as anticipated we may suffer continued poor performance in U.S. sales and further harm to our business and financial condition.

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 affects 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.

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 could experience losses due to product liability claims.

We have been subject to product liability claims in the past and may experience such claims in the future. 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, AMO, and Bausch & Lomb have much greater financial resources than we do and some of them have large international markets for a full suite of ophthalmic products. Their greater resources for

research, development and marketing, and their greater capacity to offer comprehensive products and equipment to providers, make it difficult for us to compete. We have lost significant market share to some of our competitors.

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 fiscal year ended January 2, 2009 sales from international operations were 75% of our total sales. The results of operations and the financial position of certain of our foreign operations are reported in the relevant local currencies and then translated into U.S. dollars at the applicable exchange rates for inclusion in our consolidated financial statements, exposing us to 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, the Australian dollar, and the Japanese Yen. The exchange rates between these and other local currencies and the U.S. 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.

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 U.S. 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 integrate its foreign subsidiaries fully 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, language differences and the local legal climate can result in misunderstandings among internationally dispersed personnel, and increase the risk of failing to meet U.S. and foreign legal requirements, including with respect to the Sarbanes-Oxley Act of 2002 and the U.S. Foreign Corrupt Practices Act. These risks have increased now that we have completed the acquisition of STAAR Japan, Inc. The risk that unauthorized conduct may go undetected will always be greater in foreign subsidiaries.

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. 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. Even when secondary sources are available, 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 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. 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 an 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 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, motivate and retain other highly skilled personnel. Failure to do so may adversely affect our results.

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, which could result in significant change to our reported results of operation or financial condition.

We are subject to international tax 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. 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 our manufacturing facilities in California, Japan 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. Our California and Japanese 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. Our insurance for property damage and business interruption may not be sufficient to cover any particular loss, and we do not carry insurance or reserve funds for interruptions or potential losses arising from earthquakes or terrorism.

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

We manufacture all of our products at our facilities in California, Switzerland, and Japan. 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.

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 recall a product, the cost and damage to our reputation could harm our business.

Medical devices must be manufactured to the highest standards and tolerances, and often incorporate newly developed technology. From time to time defects or technical flaws in medical devices may not come to light until after the products are sold or consigned. In those circumstances, like others in our industry, we have voluntarily recalled our products. Similar recalls could take place again. We may also be subject to recalls initiated by manufacturers of products we distribute. Courts or regulators can also impose mandatory recalls on us, even if we believe our products are safe and effective. STAAR believes that in recent years it has been less affected by recalls than most of its U.S. competitors, but cannot eliminate the risk of a material recall in the future. 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 professionals to discontinue using our products.

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 superior product, or if we announce a new product of our own. If we fail to make sufficient investments in research and development or if we focus on technologies that do not lead to better products, our current and planned products could be surpassed by more effective or advanced products. In addition, we must manufacture these products economically and market them successfully by persuading a sufficient number of eye-care professionals to use them. For example, glaucoma requires ongoing treatment over a long period; 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 11% of our sales on research and development during the fiscal year ended January 2, 2009, and we expect to spend approximately 7-10% of our sales 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. Any of the products currently under development may fail to 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 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. For example, the Centers for Medicaid and Medicare have recently reduced the reimbursement rate for glaucoma procedures such as the implantation of our AquaFlow Device. In some countries government insurers have sought to control costs by limiting the total number of procedures they will reimburse. 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 significantly and adversely affect 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 any rebates we may offer to customers. Complying with government regulation substantially increases the cost of developing, manufacturing and selling our products.

In the U.S., we must obtain approval from the FDA for each product that we market. Competing in the ophthalmic products industry requires us to introduce new or improved products and processes continuously, 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 are subject to periodic inspection by the FDA and international regulators. 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.

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 timely 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.

Investigations and allegations, whether or not they lead to enforcement action or litigation, can materially harm our business and our 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 distribute our products commercially and could materially harm our business.

From time to time STAAR is subject to formal and informal inquiries by regulatory agencies, which could lead to investigations or enforcement actions. Even when an inquiry results in no evidence of wrongdoing, is inconclusive or is otherwise not pursued, 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 report any violation of laws, regulations or company policies anonymously, which is intended to permit STAAR to identify and remedy improper conduct. Nevertheless, present or former employees may elect to bring complaints including 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. In response to reports that its policies or applicable laws or regulations have been violated, STAAR may find it necessary to conduct its own intense investigations, which may be extensive. Even without a finding of misconduct, negative publicity about investigations or allegations of misconduct could harm our reputation with professionals and the market for our common stock. Responding to investigations or conducting internal investigations can be costly, time-consuming and disruptive to our business.

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

We rely on patents, trademarks, trade secrecy laws, contractual provisions and confidentiality procedures and copyright 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. Any of our pending patent applications may fail to result in an issued patent or fail to 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 open to dispute. Any litigation or claims against us, whether or not successful, could result in substantial costs and harm our reputation. Intellectual property litigation or claims could force us to do one or more of the following:

- cease selling or using any of our products that incorporate the challenged intellectual property, which would adversely affect our sales;

- 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

- redesign our products to avoid infringing the intellectual property rights of a third party, which may be costly and time-consuming or impossible to accomplish.

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

Most of our products are covered by patents that, if valid, 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 reduce our prices to maintain sales of our products, which would make them 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 charter documents 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 could be deemed in the interest 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