STAAR SURGICAL CO
Form 10-K
April 01, 2010

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 1, 2010

or

¨ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from to

Commission file number: 0-11634

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

Delaware	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 ¨ 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 ¨ 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 ¨

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ¨ No ¨

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, 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):

¨ Large accelerated filer	þ Accelerated filer	¨ Non-accelerated filer	¨ 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 ¨ No þ

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant as of July 3, 2009, the last business day of the registrant's most recently completed second fiscal quarter, was approximately $80,835,000 based on the closing price per share of $2.33 of the registrant's Common Stock on that date (used actual close price on July 2, 2009 as markets were closed on July 3, 2009).

The number of shares outstanding of the registrant's Common Stock as of March 29, 2010 was 34,866,728.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement relating to its 2010 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

A glossary of terms used in the Report may be found on page 15.

General

STAAR Surgical Company designs, develops, manufactures and sells implantable lenses for the eye. We make lenses both for use in surgery that treats cataracts, and for use in corrective or "refractive" surgery. All of the leases we make are foldable, which permits the surgeon to insert them through a small incision in minimally invasive surgery. Cataract surgery is a relatively simple outpatient procedure where the eye's natural lens is removed and replaced with an artificial lens called an intraocular lens (IOL) to restore the patient's vision. Refractive surgery is performed to correct the type of visual disorders that have traditionally been treated with glasses or contact lenses. We refer to our lenses used in refractive surgery as "implantable Collamer® lenses" or "ICLs." Refractive surgery includes lens-based or laser-based procedures. Successful refractive eye surgery can correct common vision disorders such as myopia, hyperopia and astigmatism. 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®, Visian®, Collamer®, nanoFLEX™, nanoPOINT™, STAARVISC®, Elastimide®, and AquaFlow™ are trademarks or registered trademarks of STAAR in the U.S. and other countries. Collamer® is the brand name for STAAR's proprietary collagen copolymer lens material.

Intraocular lenses. We generate approximately half of our sales manufacturing and selling foldable 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 manufactures 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. STAAR also markets internationally an independently sourced acrylic IOL, preloaded using STAAR technology. 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. Astigmatism is a condition that causes blurred vision due to the irregular shape of the cornea which prevents light from focusing properly on the retina;

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

- Aspheric IOLs, available in silicone or Collamer, designed to provide a clearer image than traditional spherical IOLs, by reducing spherical aberrations and improving contrast sensitivity;

- The nanoFLEX IOL, a single-piece Collamer aspheric IOL that can be implanted through a 2.2 mm incision with the nanoPOINT injector system.

Implantable Collamer lenses. Manufacturing and selling lenses used in refractive surgery is an increasingly important source of sales for STAAR. We have used our proprietary biocompatible Collamer material to develop and manufacture implantable Collamer lenses, or ICLs. STAAR's VISIAN ICL and VISIAN Toric ICL, or TICL™, treat refractive disorders such as myopia (near-sightedness), hyperopia (far-sightedness) and astigmatism. These disorders of vision affect a large proportion of the population. Unlike the IOL, which replaces a cataract patient's cloudy lens, these products are designed to work with the patient's natural lens to correct refractive disorders. The surgeon implants the foldable Visian lens through a tiny incision, under topical 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. We also sell other related instruments, devices, surgical packs and equipment that we manufacture or that are manufactured by others but began deemphasizing these products beginning in 2009 due to their lower overall gross profit margins.

Operations

STAAR has significant operations both within and outside the U.S. Sales from activities outside the U.S. accounted for 79% of our total sales in fiscal year 2009. 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 a facility in Aliso Viejo, CA.

- Switzerland. STAAR operates an administrative, manufacturing and distribution 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 the AquaFlow Device. STAAR Surgical AG handles distribution and other administrative affairs for Europe and other territories outside North America and Japan.

- Japan. STAAR operates administrative, manufacturing and distribution facilities in Japan under its wholly owned subsidiary, STAAR Japan Inc. STAAR Japan's administrative and distribution facility is located in Shin-Urayasu and its manufacturing facility in located in Ichikawa City. All of STAAR's preloaded injectors are manufactured at the Ichikawa City facility. Following its approval by the Japanese Ministry of Health, Labor and Welfare on February 2, 2010, STAAR Japan began marketing and distributing the Visian ICL in Japan.

- Germany. Until March 2, 2010, STAAR owned Domilens GmbH ("Domilens"), 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 has distributed STAAR's IOLs, ICLs and Preloaded Injectors in Germany. On March 2, 2010, STAAR sold all of its interests in Domilens through a management buyout led by funds managed by Hamburg-based Small Cap Buyout Specialist BPE Unternehmensbeteiligungen GmbH. STAAR and Domilens have entered into a Distribution Agreement providing for the continued sale of STAAR products in Germany and Austria. The sale of Domilens is discussed in greater detail in Management's Discussion and Analysis of Financial Condition and Results of Operations.

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 depend 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 interior surface of the cornea is lined with a single layer of flat, tile-like endothelial cells, whose function is to maintain the transparency of the cornea. 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 medical term for the natural lens that is present in the eye from birth is “crystalline lens. ” 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, 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 anterior chamber is the space in the eye behind the cornea and in front of the iris. 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. One of the most prevalent ocular disorders is cataracts. 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 Visian 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. 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 received CE Marking in 1997, permitting sale 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 150,000 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.

- 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 Visian ICL for the treatment of myopia, making it the first, and to date only, small incision phakic IOL commercially available in the United States.

- Beginning in 2007, STAAR introduced its first aspheric IOLs made of silicone and Collamer and has received New Technology IOL "NTIOL" designation which qualify them for an additional $50 reimbursement through February 26, 2011.

    - On December 29, 2007 (fiscal 2008), we acquired the 50% remaining interests in STAAR Japan.

- On February 2, 2010, the Japanese Ministry of Health, Labor and Welfare approved the Visian ICL, making it the first phakic IOL available for sale in Japan.

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 18 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. Surgeons prefer foldable lenses and small incisions because clinical evidence has overwhelmingly shown that larger incisions can induce corneal astigmatism, extend healing times, and increase the possibility of infection. Once inserted, the IOL unfolds naturally to replace the cataractous lens.

In most countries a process of government reimbursement for cataract surgery and IOLs exist. In some countries the ability for ophthalmic surgeons and surgical centers to collect an additional fee from the patients is evolving. STAAR's strategic direction is to offer additional IOLs that fall within the categories which offer an opportunity to increase average selling prices. As an example here is the pricing landscape in the U.S. for IOLs today:

- Standard or conventional IOLs are reimbursed by the Center for Medicare and Medicaid Services ("CMS ") at a rate of approximately $150. STAAR's non-aspheric silicone and Collamer IOLs fall within this category.

- IOLs with New Technology Intraocular Lens ("NTIOL") designation by CMS are reimbursed an additional $50 or about $200 when implanted at Ambulatory Surgical Center facility. STAAR's new aspheric silicone and Collamer IOLs fall within this category.

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Premium channel IOLs are reimbursed at the standard IOL rate by CMS plus an additional payment is allowable from the patient. STAAR's Silicone Toric IOL falls within this category.

Currently, our foldable IOLs are manufactured from both our proprietary Collamer material and silicone. Both materials are offered in two differently configured styles: the single-piece plate haptic design and the three-piece design where the optic is combined with Polyimide™ loop haptics. The selection of one style over the other is primarily based on the preference of the ophthalmologist. We also market foldable IOLs packaged in a preloaded delivery system with an independently sourced acrylic lens in various markets outside the U.S.

STAAR'S development efforts have led to the introduction of aspheric IOLs beginning in 2007. 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 NTIOL designation for both products in 2008 which qualify them for additional reimbursement. During 2009, STAAR introduced the nanoFLEX IOL, which has NTIOL approval and can be delivered through a 2.2 mm micro-incision using STAAR's new nanoPOINT Injection System.

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.

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. The acrylic Preloaded Injector is now sold in Europe and other Asian countries as well. Nidek also assembles and sells 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.

Sales of IOLs accounted for approximately 45% of our total sales for the 2009 fiscal year, 44% of our total sales for the 2008 fiscal year and 39% of total sales for the 2007. Domilens has accounted for a significant portion of our sales of IOL products or approximately 22% in 2009. The sale of Domilens on March 2, 2010 is expected to increase the percentage of our sales derived from IOL products.

Visian ICL (ICLs). ICLs are implanted into the eye in order to correct refractive disorders such as myopia, hyperopia and astigmatism. The ICL is capable of correcting refractive errors over a wide 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.

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. The ICL for myopia was approved for sale in Japan on February 2, 2010, and an application is pending in Australia. 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 and it is currently under review (see "Regulatory Matters – Regulatory Requirements in the United States – Status of Toric ICL Submission").

The Hyperopic ICL, which treats far-sightedness, 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 outside the U.S. the HICL for hyperopia is available 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 29% of our total sales for the 2009 fiscal year, 25% in the 2008 fiscal year and 26% in 2007 fiscal year. The sale of Domilens on March 2, 2010 is expected to increase the percentage of our sales derived from ICLs.

Other Surgical Products

The Company also sells other related instruments, devices, surgical packs and equipment that we manufacture or that are manufactured by others, but has been deemphasizing these products in recent quarters due to their lower overall gross profit margins.

Sales of other surgical products accounted for approximately 26% of our total sales for the 2009 fiscal year, 31% of our total sales for the 2008 fiscal year fiscal year and 35% of total sales for the 2007 fiscal year. Domilens has accounted for a significant portion of our sales of other surgical products or approximately 81% in 2009. The sale of Domilens on March 2, 2010 is expected to reduce significantly the percentage of our sales derived from other surgical products.

German Distribution Business

During fiscal year 2009 STAAR owned Domilens, a German ophthalmic distribution company. Domilens principally resells and services products manufactured by third parties, along with STAAR's ICLs and Preloaded Injectors. Domilens generates substantially all of its sales from the ophthalmic surgical products market. Domilens reported sales of $24.3 million in fiscal year 2009, $25.1 million in fiscal year 2008 and $23.7 million in fiscal year 2007. STAAR sold all of its interests in Domilens on March 2, 2010.

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. We try to mitigate this risk by maintaining high inventory of 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, 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. In addition, the loss of our external supply source for silicone could cause us material harm.

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 1, 2010, we owned approximately 128 United States and foreign patents and had approximately 12 patent applications pending.

The Company considers its patents to be significant when they protect the exclusivity of its material products in the marketplace or provide an opportunity to obtain material royalties or cross-licenses of intellectual property from other manufacturers. Because the Company has limited knowledge of the research and development efforts and strategic plans of its competitors, it can only estimate the value of its patents and the significance of any particular patent's

expiration. Competitors may be able to design products that avoid infringing on patents that the Company regards as valuable, or they may find patents that the Company regards as less significant to be obstacles to their development of competing products. The Company's internal assessments of its patents include confidential information, the disclosure of which would cause significant competitive harm to the Company.

The Company's material patents generally fall within three areas of technology: (1) design of a posterior chamber phakic intraocular lens used to treat refractive errors of the eye (ICLs), (2) the Collamer® lens material, and (3) lens delivery systems for folding intraocular lenses (injectors and cartridges).

Posterior Chamber Phakic Intraocular Lens to treat Refractive Errors

The Company's Visian ICL is the only posterior chamber phakic IOL approved for sale in the U.S., and the Company believes it is the world's largest selling phakic IOL. The Company believes that its leadership in commercializing this technology results from a number of factors, including proprietary design features and the biocompatibility of the Collamer material. (The proprietary nature of Collamer is discussed in further detail below).

The Company has several patents covering design features that the Company believes are essential to the safety and effectiveness of its phakic IOLs, and that the Company believes would be necessary or desirable for any competing posterior chamber phakic IOL. These patents expire between 2014 and 2016.

Collamer Lens Material

The Company believes that the biocompatibility of the Collamer material used for the Visian ICL (and TICL) is a significant factor in the ability to safely place this lens in the posterior chamber of the eye. Because the Visian ICL is well tolerated in the eye, complications that have prevented the introduction of other posterior chamber PIOL designs are less likely to occur. Compared to lenses placed in the anterior chamber, the Company believes that placement in the posterior chamber provides superior optical results and superior cosmetic appearance, poses less risk of damage to the cornea, and better allows for the correction of a patient's astigmatism through the use of toric optics.

The Company believes that the physical and optical properties of Collamer also give it distinct advantages as a material for prosthetic IOLs used in cataract surgery.

Collamer belongs to a family of materials known as collagen copolymers. Collagen copolymers are compounds formed by joining molecules of collagen derived from biological sources with synthetic monomer molecules. The patents that underlie the specific Collamer formulation and manufacturing methods expire between 2014 and 2016.

The Company also held an exclusive license throughout most of the world on an early patent on a biocompatible collagen copolymer for ophthalmic use, which was acquired from the Federov Institute of Russia in 1996, and which patent expired in November 2009. Because the Collamer material is a different collagen copolymer formulation with improved optical and physical characteristics, which is covered by the subsequent STAAR patents described above as well as significant trade secrets, STAAR does not believe that the expiration of the Federov patent has materially diminished the proprietary nature of the Collamer material.

Lens Delivery Systems

STAAR owns numerous patents covering the technology of foldable lens delivery systems, including injectors, cartridges and preloaded injectors and their specific design features. This group of patents includes relatively recent patents with up to 10 years of life remaining. However, a select group of these patents covering the more fundamental lens delivery technologies will expire between 2012 and 2014.

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.

The first quarter of each fiscal year tends to have the lowest cash flow of the year because of accounting fees related to the annual audit of our financial statements, professional fees for our consultant on internal controls pursuant to the Sarbanes-Oxley Act of 2002, and holiday closures of facilities during December that reduce the processing and payment of invoices by STAAR during the last weeks of the fourth quarter, resulting in a significant increase in cash payments by STAAR as it catches up during the first month of the first quarter.

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 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 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.

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: Alcon Laboratories ("Alcon"); Abbott Medical Optics ("Abbott"), previously known as Advanced Medical Optics ("AMO"); and Bausch & Lomb. 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 ICL and the

Ophtec Artisan®, also Verisyse™ marketed by Abbott. In international markets, our ICL's main competition is the Verisyse/Artisan lens, although there are several other phakic IOLs, manufactured by various companies that are also available.

We believe our primary competitors in the development and sale of products used to surgically correct cataracts, specifically foldable IOLs, include Alcon, Abbott and Bausch & Lomb. According to a 2009 Market Scope report, Alcon holds 54% of the global IOL market, followed by Abbott with 16% and Bausch & Lomb with 10%. Market Scope estimates STAAR's global revenue market share at 2.3%. We hold approximately 8% to 9% market share in both Germany and Japan and approximately 3% 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.

According to Market Scope, acrylic, which is marketed as an advanced material, is the most preferred material for an IOL in the world, followed by silicone and PMMA. Acrylic IOLs currently account for a 79% 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 in 2009 introduced the nanoFLEX IOL which can be delivered using STAAR's nanoPOINT™ injector, through a 2.2 mm incision.

Outside the U.S. STAAR markets the KS-X IOL line, which mates STAAR's proprietary preloaded delivery system with an independently sourced acrylic lens. The KS-X preloaded delivery system enables the lens to be delivered into the eye through a 2.8 millimeter incision. The lens material used is a hydrophobic acrylic which is the material preferred by most surgeons on the market.

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. 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. 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). 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. NTIOL designation for aspheric IOLs that demonstrate improved visual performance extends until February 26, 2011.

Although the market for silicone IOLs, which currently account for 18% 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 2010 introduction of preloaded injectors to deliver this lens will enhance STAAR's ability to maintain market share within the silicone market sector.

"Presbyopic IOLs" sold by our major U.S. competitors are lenses that offer to make patients less dependent on reading glasses or contact lenses to provide near and far vision after cataract surgery. FDA-approved and CE-marked lenses of this type include a lens produced by Bausch & Lomb that has been found to restore some of the eye's natural ability to focus, and multifocal lenses produced by Alcon and AMO that create zones in the visual field for distance, far and near vision, similar to the near and far zones in bifocal glasses. In the U.S., CMS rules permit a cataract patient implanted with a presbyopic lens to receive reimbursement at the rate allowed for surgery with a standard IOL, and to pay out of pocket the balance of the lens cost and surgical fee for the premium presbyopic IOL. Presbyopic lenses have gained significant share of the overall IOL marketplace. STAAR plans to conduct clinical tests to substantiate the accommodating performance of its current nanoFLEX lens and on a new IOL designed to optimize the potential accommodating power of the Collamer IOL platform. However, at present, STAAR does not have a product approved by the FDA for the treatment of presbyopia in order to compete in this market sector.

Regulatory Matters

Nearly all countries where we sell our products have regulations requiring advance approval or certification of medical devices. 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 requirements for approval or clearance to market medical products vary widely by country. The requirements range from minimal requirements to requirements comparable to those established by the U.S. Food and Drug Administration ("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 process of obtaining approval to distribute medical products is costly and time-consuming in virtually all of the major markets where we sell medical devices. We cannot assure that any new medical devices we develop will be approved in a timely or cost-effective manner or approved at all. The regulatory requirements in our most important current markets, the U.S., Europe and Japan, are discussed below.

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 of 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. The FDA reviews device applications and notifications through its Office of Device Evaluation, or "ODE."

510(k) Clearance. 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 under Section 510(k) of the Act 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.

After a device receives 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, will require a new 510(k) clearance or could require premarket approval. The FDA requires each manufacturer to make its own initial determination as to whether a change significantly affects safety or effectiveness. However, the FDA can review any such decision and can disagree with a manufacturer's determination. If the FDA disagrees with a manufacturer's determination, the FDA can require the manufacturer to cease marketing or recall the modified device until 510(k) clearance or premarket approval is obtained. If the FDA requires us to seek 510(k) clearance or premarket approval for any modifications to a previously cleared product, we may be required to cease marketing or recall the modified device until we obtain this clearance or approval. Also, in these circumstances, we may be subject to significant regulatory fines or penalties.

In September 2009 the FDA requested that the Institute of Medicine perform a study on whether legislative, regulatory or administrative changes are needed to the FDA's 510(k) process. The Institute of Medicine report is due in March 2011. The FDA also announced an internal working group to evaluate and improve the consistency of FDA decision making in the clearance process, and recently released an internal report in which FDA officials questioned the 510(k) process in general. Various committees of the U.S. Congress also have indicated that they may consider investigating the FDA's 510(k) process. If these actions result in a limitation or elimination of the 510(k) approval path STAAR may find it much more costly and time consuming to develop and introduce new products in the U.S.

Premarket Approval. When 510(k) clearance is not available, the more rigorous PMA process requires us to independently demonstrate that the new medical device is safe and effective. As an initial step the process of developing the product must be stringently managed and documented – along with any later changes in design – in a "design history file" that will be submitted with the PMA. The next step is pre-clinical testing, which includes chemical analysis, toxicity testing and other bench testing, and animal trials. The results of this early testing are submitted to the FDA along with a detailed research plan. Only after approval of this submission can a non-approved device receive an "investigational device exemption" or IDE, which permits the device to be used to treat human subjects in a supervised study.

Clinical trials on human subjects are expensive and time consuming, often taking years from design to completion. The FDA must approve in advance any use of an unapproved device – an "investigational device" or IDE – in human clinical trials, and approves the design of the related study. The trial, once approved, is subject to extensive oversight. In addition to FDA oversight through the ODE and the FDA's Division of Bioresearch Monitoring ("BIMO"), the company sponsoring the research must designate a private Independent Review Board ("IRB") to approve and monitor the research and assure that it is ethical, scientifically sound and regulated. The company sponsoring the research must adopt and observe stringent procedures for overseeing research, collecting and analyzing data, and will be subject to BIMO audits to verify compliance.

If clinical research supports the safety and efficacy of the device, the sponsor prepares and submits the PMA, which consists of several volumes and includes not only research data and analysis, but also design history files. In addition to its own review, the FDA may organize an independent advisory panel of experts to review the PMA whenever a device is the first of its kind or the FDA otherwise determines panel review is warranted. Panels are held on a regular basis, but the need to schedule panel review usually adds some weeks or months to the review process.

Following its review, the FDA will authorize commercial release if it determines there is reasonable assurance that the medical device is safe and effective. This FDA decision is based on a determination that the device's benefit outweighs the risk to the population for which treatment with the device is intended.

If a manufacturer plans to modify an approved PMA device in a manner that affects safety or effectiveness, the manufacturer must submit an application called a "PMA Supplement" regarding the change. The FDA generally reviews PMA Supplements on a 180-day agency timetable, which may be extended if significant questions arise in review of the supplement. A change that enhances safety may be implemented prior to the FDA's review of the PMA Supplement. The FDA designates some PMA Supplements as "panel track" supplements, which means that the agency believes review by an advisory panel may be warranted. Designation as a panel-track supplement does not necessarily mean that panel review will actually occur; often it does not.

Our IOLs, ICLs, and AquaFlow Devices are Class III devices, and our lens injectors are Class I devices. We have received PMA approval for our IOLs, the ICL for the treatment of myopia, and the AquaFlow Device. We have received 510(k) clearance for our lens injectors.

Oversight of compliance with quality, medical device reporting and other regulations. Both before and after a product is commercially released, we have ongoing responsibilities under FDA regulations. The FDA Office of Compliance reviews design and manufacturing practices, labeling and record keeping, and manufacturers' required reports of adverse experiences and other information to identify potential problems with marketed medical devices. We are also subject to periodic inspection by the FDA for compliance with the FDA's quality system regulations as well as other FDA requirements, such as restrictions on advertising and promotion. The GMP regulations govern the methods used in, and the facilities and controls used for, the design, manufacture, packaging and servicing of all finished medical devices intended for human use. If the FDA were to conclude that we are not in compliance with applicable laws or regulations, or that any of our medical devices are ineffective or pose an unreasonable health risk, the FDA could require us to notify health professionals and others that the devices present unreasonable risks of substantial harm to the public health, order a recall, repair, replacement, or refund of such devices, detain or seize adulterated or misbranded medical devices, or ban such medical devices. The FDA may also impose operating restrictions, enjoin and restrain certain violations of applicable law pertaining to medical devices, and assess civil or criminal penalties against our officers, employees, or us. The FDA may also recommend prosecution to the Department of Justice.

BIMO Review of Clinical Research Activities. Our activities as a sponsor of clinical research are subject to review by the FDA's BIMO division. BIMO conducts facilities inspections as part of a program designed to ensure that data and information contained in requests for IDEs, PMA applications, and 510(k) submissions 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.

Recent FDA Reviews of STAAR's Quality Systems. The FDA's most recent general quality inspections of STAAR's facilities were regularly scheduled inspections of the Nidau, Switzerland facility between June 2 and June 5, 2009, the Monrovia, California facility, between February 23 and March 4, 2009, and a post-market inspection of the Aliso Viejo, California facility on August 7, 2006. The recent inspection of the Nidau, Switzerland facility that concluded on June 5, 2009 resulted in the inspector issuing two observations of nonconformity on Form FDA-483. STAAR agreed with the observations and at the conclusion of the inspection both of the observations were annotated as corrected and one was additionally annotated as verified. 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 corrective actions to address each observation. We prepared and submitted 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 inspection of Aliso Viejo, California resulted in no observations of noncompliance. Based in part on these inspections, 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 to continue to devote significant resources and attention to those efforts.

Recent BIMO Review of STAAR's Clinical Research Activities. BIMO conducted an inspection related to STAAR's TICL supplemental premarket application between February 15, 2007 and March 14, 2007, which resulted in eight inspectional observations. On June 26, 2007, BIMO issued a Warning Letter in which it noted four areas of noncompliance in STAAR's clinical research procedures and data reporting. The BIMO observations and Warning Letter also resulted in the ODE placing STAAR's TICL application on integrity hold notwithstanding STAAR's written

responses to the observations and Warning Letter, on August 3, 2007.

In order to address BIMO's concerns and remove the integrity hold, STAAR took a number of corrective actions, including engaging an independent third party auditor to conduct an audit of patient records in the TICL clinical study, along with an audit of clinical systems to ensure accuracy and completeness of data before resubmitting the application. Following submission of the third party auditor's reports to FDA in late 2008, the reports were released to STAAR in 2009 and STAAR submitted a corrective action plan to address the reported findings. On July 21, 2009, the FDA notified STAAR that as a result of various corrective actions the integrity hold had been removed and that consideration of the TICL application would resume.

While the past instances of noncompliance with procedures noted in the BIMO Warning Letter were serious in nature and required comprehensive corrective and preventative actions, STAAR does not believe that these nonconformities undermined the scientific validity and accuracy of its clinical data, or that human subjects were subjected to undue hazard or risk. STAAR believes that its corrective actions have substantially remedied BIMO's concerns. However, in releasing the integrity hold, the FDA noted that for a period of two years it will require STAAR to obtain certification from an independent third party auditor for some of its filings. This requirement may increase the cost and time necessary for some FDA submissions.

Status of TICL Submission. STAAR submitted a Pre-Market Approval Application (PMA) supplement for the TICL to the FDA on April 28, 2006. The FDA's consideration of the application, which has been designated as a panel-track supplement, was suspended on August 3, 2007, when the FDA notified STAAR of the integrity hold. Among the actions required to resolve the integrity hold was an independent third party audit of patient records in the TICL clinical file, along with a clinical systems audit to ensure accuracy and completeness of data before resubmission of the application.

The third party auditors completed their audits and submitted reports of their findings directly to the FDA in late 2008. The reports were released to STAAR in 2009 and STAAR completed a corrective action plan to address the reported findings. The corrective action plan was submitted to the FDA on May 25, 2009. On July 21, 2009 the FDA removed the integrity hold and resumed substantive review of the TICL application. Subsequent to the release from integrity hold, the FDA and STAAR resolved a number of questions related to the TICL supplement in an interactive process during August and September.

On February 3, 2010, STAAR received a letter of deficiency from the FDA outlining additional questions and requested labeling changes related to the TICL application. The letter provides that STAAR has 180 days to present its response to the FDA; STAAR is actively working on the preparation of the comprehensive response to the items in this letter.

Regulatory Requirements outside the United States.

CE Marking. 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 on a medical device indicates that it has been found to comply with European Directives and associated guidelines concerning the design and manufacture of medical devices, including clinical trials, labeling, quality control, technical specifications, adverse event reporting, and biological, 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.

A CE Marked device may be sold throughout the 27 countries in Europe. Other countries, such as Switzerland, have voluntarily adopted laws and regulations that mirror those of the European Union with respect to medical devices, and a number of countries outside of Europe permit importation of devices bearing the CE Mark. The method of assessing conformity varies depending on the class of the product, but normally involves a combination of self-assessment by the manufacturer and a third-party assessment by a "Notified Body." Notified Bodies are a group of private quality-monitoring organizations that have been accredited to approve medical devices and to monitor quality systems and adverse event reporting. The independent Notified Bodies perform, on a privatized basis, functions similar to the FDA in the U.S. and the PMDA in Japan. Our facilities in the U.S., Japan and Switzerland are all subject to regular inspection by a designated Notified Body.

Medical Device Regulation in Japan. The Japanese Ministry of Health, Labor, and Welfare (MHLW) regulates the sale of medical devices under Japan's Pharmaceutical Affairs Law (PAL). The Pharmaceutical and Medical Devices Agency (PMDA), a quasi-governmental organization, performs many of the medical device review functions for MHLW. Medical devices generally must undergo thorough safety examinations and demonstrate medical efficacy

before the MHLW grants shonin (pre-market device approval) or ninsho (certification). Manufacturers and resellers (referred to as Marketing Authorization Holders or MAHs) must also satisfy certain requirements before the MHLW grants a business license, or kyoka. Requirements for manufacturers and MAHs include compliance with Japanese regulations covering GQP (good quality control practice) and GVP (good vigilance practice), which include conformity to the ISO 13485 standard and are similar to good manufacturing practice and post-market surveillance requirements in the U.S., as well as the assignment of internal supervisors over marketing, quality assurance and safety control.

Approval for a new medical device that lacks a substantial equivalent in the Japanese market will generally require the submission of clinical trial data. Only a licensed MAH can apply for premarket device approval in Japan, and in most cases the clinical trial data must include data gathered from Japanese subjects. For example, STAAR Japan conducted a separate clinical trial in Japan for the shonin application for the Visian ICL. Also, approval for a new medical device will require the manufacturer to undertake to reexamine the safety and efficacy of the device with a review of postmarket data gathered within a certain period - normally four years - after approval. The specific postmarket reexamination requirement for a medical device is announced at the time of approval.

STAAR Japan currently holds shonin approval for the Visian ICL, preloaded injectors and their associated lenses, and kyoka licensing as a manufacturer and MAH of medical devices. The sponsor of a clinical trial submitted to the MHLW must strictly follow Good Clinical Practice (GCP) standards, and must follow the trial with standard Good Postmarket Study Practice (GPSP) reporting and a follow-up program. MHLW and PMDA also assess the quality management systems of manufacturers and the conformity of products to the requirements of PAL. STAAR is subject to inspection for compliance by these agencies. A company's failure to comply with PAL can result in severe penalties, including revocation or suspension of a company's business license and possible criminal sanctions.

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 46 employees. In order to achieve our business objectives, we will continue the investment in research and development.

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 and in 2009 introduced the Epiphany injector system to the U.S. market. 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 STAAR introduced the nanoFLEX™ Aspheric Collamer IOL, which can be delivered through the nanoPOINT injector, and the advanced Epiphany™ injector system for the Afinity Collamer IOL. Outside the U.S. STAAR introduced the KS-X Preloaded Hydrophobic Acrylic Injector System in Europe and the KS-Ni Preloaded Silicone IOL Injector System in Japan.

The introduction of the nanoFLEX IOL provided the opportunity to evaluate the near and intermediate vision provided by this new lens. A group of eight surgeons referred to as the Collamer Accommodating Study Team or "CAST" implanted the lens in both eyes of their patients and tested these patients for distance corrected near and intermediate visual acuity using a calibrated reading card. The result of this evaluation indicated that the nanoFLEX IOL provides better best distance corrected near vision than other standard IOLs on the market and better distance corrected intermediate vision than premium IOLs. Based on these encouraging results STAAR is organizing a formal clinical study where the distance corrected near and intermediate vision of nanoFLEX IOL patients will be evaluated with the objective of gaining FDA approval for a labeling claim.

During 2010 our goal is to continue our focus on research and development in the following areas:

- Introduction of the silicone preloaded injector system in the U.S.
- Introduction of a small incision injector system for ICLs

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- Continue development of a Collamer Toric IOL to complement our pioneering silicone Toric IOL
- Development of accommodating or presbyopic IOLs
- Development of preloaded injector systems for Collamer IOLs and ICLs

Research and development expenses were approximately $5.9 million, $7.9 million, and $6.7 million for our 2009, 2008 and 2007 fiscal years, respectively. STAAR expects to invest approximately 10% of sales for research and development in 2010.

Environmental Matters

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

Significant Subsidiaries

As of March 15, 2010, the Company’s principal and wholly owned subsidiaries were STAAR Surgical AG and STAAR Japan Inc. The activities of each are described above.

Employees

As of March 15, 2010, we employed approximately 296 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.

Glossary

The following glossary is intended to help the reader understand some of the terms used in this Report.

accommodation – the eye's ability to adjust its focus at all distances between near and far. This ability tends to decline with age.

accommodating IOL – a type of IOL designed to restore some degree of variable near-and-far focus after cataract surgery.

acrylic – a broadly used family of plastics. Acrylic materials used in IOLs have been both water repelling (hydrophobic) and water-absorbing (hydrophilic). The most popular IOLs in the U.S., Europe and Japan are made of a flexible, water-repellent acrylic material.

anterior chamber – the space in the eye between the cornea and the iris.

aspheric – aspheric lenses are lenses that are designed in a shape that creates a more clearly focused image than traditional spheric lenses. By reducing spheric aberrations, IOLs that feature aspheric optics generally deliver better night vision and contrast sensitivity than spheric IOLs.

astigmatism is a refractive disorder in which partially blurred vision results from an irregularly shaped cornea or, in some cases, a defect in the natural lens, produces a distorted image on the retina. The astigmatic eye is sometimes said to be slightly football-shaped rather than being a perfect sphere.

cataract – a common age-related eye disorder that involves the hardening and loss of transparency of the natural crystalline lens, impairing visual acuity.

CMS – the Centers for Medicare and Medicaid Services, the U.S. federal agency that administers and establishes rules for the Medicare and Medicaid reimbursement systems.

collagen copolymer - collagen copolymers are compounds formed by joining molecules of collagen derived from biological sources with synthetic monomer molecules. STAAR's Collamer® is a collagen copolymer engineered specifically for use in implantable lenses.

Collamer® - the brand name for STAAR's proprietary collagen copolymer lens material. Collamer is composed of a poly-HEMA-based copolymer, collagen and a UV-absorbing chromophore. Collamer lenses have a high water content, are biocompatible and are designed to mimic the optical properties and flexibility of the natural lens in the human eye.

contrast sensitivity - the ability to visually distinguish an object from its background.

crystalline lens – the natural lens that is present in the eye at birth, which is a clear structure located behind the iris that changes shape to focus light onto the retina.

decentration – decentration of an IOL is a displacement of an IOL after implantation in the eye such that the ICL's central axis is not perfectly aligned with the visual axis of the eye. STAAR developed its proprietary aspheric design to perform well even if decentered.

excimer laser – a specialized ultraviolet laser used in ophthalmology to cut or shape eye tissue. The excimer laser is used during LASIK and PRK surgery.

foldable IOL – an intraocular lens made of flexible material, which can be inserted with an injector system through a small incision in minimally invasive cataract surgery.

glaucoma – a progressive and degenerative condition, usually associated with elevated fluid pressure in the eye, in which the optic nerve may be damaged, resulting in irreversible loss of vision. Glaucoma is a leading cause of blindness worldwide.

haptic – the part of an IOL that contacts the structures of the eye and holds the IOL in place. IOLs in which the haptic is also a part of the optic material is called a single-piece IOL while IOLs in which the haptics are attached to the optic is called a three-piece IOL.

hyperopia – the refractive disorder commonly known as farsightedness, which occurs when the eye's lens focuses images behind the plane of the retina. A person with hyperopia cannot see close objects without glasses or contact lenses. Because presbyopia often results in the need for reading glasses, it is sometimes confused with farsightedness.

HICL – a Visian ICL product used to treat hyperopia (farsightedness).

ICL – an abbreviation for "implantable Collamer lens," the Visian ICL is a folding lens implanted in the eye to correct refractive errors like myopia that have traditionally been corrected with eyeglasses or contact lenses. The ICL is within a product category referred to as phakic IOLS or phakic implants because they work with the patient's natural lens, or phakos, rather than replacing it.

intraocular – within the eye.

iris – the muscular curtain located behind the cornea, which opens and closes to regulate the amount of light entering the eye through the pupil, which is an opening at the center of the iris. The iris carries the blue or brown pigment that gives the eye its color.

injector or injector system – a device, in the form of a syringe, that is used to deliver a foldable IOL into the eye through a slender nozzle in minimally invasive cataract surgery.

laser eye surgery – a generic term for LASIK and PRK.

LASIK – an acronym for laser-assisted in-situ keratomileusis, a surgical operation that reshapes the cornea to correct nearsightedness, farsightedness, or astigmatism. LASIK involves first the cutting of a hinged flap to separate the surface layer of the cornea, using a microkeratome (a special blade) or a laser. An excimer laser is then used to burn tissue away and reshape the inner cornea, after which the flap is returned to position.

multifocal IOL – a type of IOL that creates zones in the visual field for distance, far and near vision, similar to the near and far zones in bifocal glasses.

myopia – the refractive disorder also known as nearsightedness, which occurs when the eye's lens focuses images in front of the retina rather than on the retinal surface. A person with myopia cannot clearly see distant objects without glasses or contact lenses.

nanoFLEX – a single-piece Collamer aspheric IOL that can be implanted through a 2.2 mm incision with the complementary nanoPOINT injector system.

ophthalmologist – a surgeon who specializes in the diseases and disorders of the eye and the visual pathway related to it. Sometimes confused with optometrist, a doctor who diagnoses disorders of the eye and prescribes eyeglasses and contact lenses for refractive disorders, but does not perform surgery.

ophthalmic – of or related to the eye.

optic – the central part of an IOL, the part that functions as a lens and focuses images on the retina.

phakic IOL or phakic implant – an artificial lens that is implanted to work along with the patient's natural lens is called a phakic IOL or phakic implant, from the Greek word for lens, phakos. This is the product class to which the Visian line of products belongs. IOLs that treat cataracts are sometimes called aphakic IOLs because they are implanted in patients whose natural lenses have been removed.

phacoemulsification is a small-incision procedure used to remove a cataract patient's cloudy lens before implantation of an IOL. Phacoemulsification uses ultrasound to break up the tissue of the crystalline lens, and then uses suction to draw the tissue out through the small incision.

posterior chamber is the space in eye behind the iris.

NTIOL – an abbreviation for New Technology Intraocular Lens. The Centers for Medicare and Medicaid Services (CMS) will grant NTIOL status to IOLs that can demonstrate improved visual performance over conventional IOLs, allowing an extra $50 reimbursement per lens implanted in an ASC (ambulatory surgical center). The majority of IOL purchases in the U.S. are implanted at ASCs and reimbursed through Medicare.

Preloaded Injector - a silicone or acrylic IOL packaged and shipped in a pre-sterilized, disposable injector ready for use in cataract surgery. The conventional method of packaging IOLs requires the surgeon or an assistant to manually load each lens into an injector before surgery.

presbyopia – an age-related condition in which the crystalline lens loses its ability to focus on both near and far objects. People who have had normal vision will typically begin to need glasses for reading or other close tasks at some point after age 40 due to presbyopia.

presbyopic IOLs are IOLs that can restore some degree of near and far visual acuity after cataract surgery.

PRK – an abbreviation for photorefractive keratectomy, a surgical operation that reshapes the surface of the cornea to correct nearsightedness, farsightedness and astigmatism. PRK involves the use of an excimer laser to ablate, or burn, small amounts of tissue from the cornea. PRK differs from LASIK, which employs a flap to gain access to the corneal bed, then uses the excimer laser to shape the corneal bed rather than the surface of the cornea.

refractive disorders are visual disorders that affect the ability of the eye's optical system to create a sharply focused image. Refractive disorders include myopia (nearsightedness), hyperopia (farsightedness), astigmatism and presbyopia. These are the visual disorders that have traditionally been treated with eyeglasses and contact lenses, and more recently with refractive surgery. Glaucoma, cataracts and macular degeneration are examples of visual impairment that are not refractive disorders.

refractive market – as used in this report "refractive market" means the overall market volume for refractive surgical procedures of all kinds, including LASIK, PRK, the Visian product family and other phakic IOLs. As used in this report, the term does not does not include sales of non-surgical products like eyeglasses and contact lenses.

refractive surgery – operative procedures intended to correct or reduce refractive disorders. In addition to the implantation of the Visian ICL, common refractive surgeries include LASIK and PRK.

retina - a layer of nerve tissue at the back of the eye 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.

silicone – a type of plastic often used in implantable devices that is inert, generally flexible and water-repelling.

single-piece IOL – in a single piece IOL the haptics and the optic are fashioned from a single piece of lens material. The two principal design categories of IOLs are three-piece IOLs and single-piece IOLs.

spheric lenses – a spheric lens has surfaces that are shaped like sections of a sphere. The sphere is not an ideal shape for an optically accurate lens, but spherical surfaces have historically been the simplest lens shape to make. Spheric lenses have spheric aberrations – small errors in focus that become more pronounced at the edge of the lens When a spheric IOL is placed in the human eye, these aberrations can reduce night vision and contrast sensitivity.

three-piece IOL – a three-piece IOL has a central, disk-shaped optic and two spring-like plastic haptics attached at either side. The haptics are positioned against structures of the eye to hold the IOL in place.

toric – refers to the shape of a lens designed to correct astigmatism, which has greater refractive power in some sections of the lens than others.

TICL – an abbreviation for "Toric implantable Collamer lens," a variant of the ICL that corrects both myopia and astigmatism.

Visian – STAAR's brand name for its family of phakic intraocular lenses, including the Visian ICL, Visian TICL and Visian HICL.

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. We have identified our known, significant risk factors below.

Risks Related to Our Business

We have a history of losses which could continue in the future.

We have reported losses in each of the last several fiscal years and have an accumulated deficit of $132.1 million as of January 1, 2010. There can be no assurance that we will report net income in any future period.

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

We began generating cash from operations in 2009 after six consecutive years when our cash requirements exceeded the level of cash generated by operations. We may not be able to sustain positive cash flow, and unexpected cash needs could exceed the amount of cash we generate. Among our challenges in maintaining and increasing positive cash flow is the March 2, 2010 sale of Domilens, in which we divested one of our historical sources of cash. While we believe our capital resources and funds generated by operations are sufficient to operate our business and satisfy our obligations, if unexpected events increase our expenses or harm the performance of our business we may need to seek additional financing. We may also be presented with opportunities to expand our business that require additional financing. Should we need additional working capital, 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. Because of our history of losses STAAR may also have difficulty obtaining debt financing on acceptable terms. An inability to secure additional financing if it is needed in the future could require us to forego opportunities for expansion, reduce exiting operations, or even jeopardize our ability to continue operations.

Our defined benefit pension plans are currently underfunded and we may be subject to significant increases in pension benefit obligations under those pension plans.

We sponsor two defined benefit pension plans through our wholly owned Swiss and Japanese subsidiaries. Both plans are underfunded and may require significant cash payments. We contributed $238,000 to our Swiss Plan and $76,000 to our Japan Plan during 2009.

Beginning October 1, 2009, as part of the Amendment of the Japan Plan discussed in Note 12 to the consolidated financial statements included in this report, STAAR Japan will maintain and administer the Japan Plan, including paying the pension benefits as they are due solely from its continuing operations. STAAR Japan is not required to, and does not expect to make any contributions to the Japan Plan in order to meet future pension benefit obligations. Therefore, STAAR Japan has no plan assets now and does not expect to have any in the future.

STAAR determines its pension benefit obligations and funding status using many assumptions, such as inflation, investment rates, mortality, turnover and interest rates, as applicable, any of which could prove to be different than projected. If the investment performance does not meet our expectations, or if other actuarial assumptions are modified, or not realized, we may be required to contribute more than we currently expect and increase our future pension benefit obligations to be funded from our operations.

Our pension plans in the aggregate are underfunded by approximately $2.0 million ($0.9 million for the Japan Plan and $1.1 million for the Swiss Plan) as of January 1, 2010 (based on the actuarial assumptions used for FASB ASC 715-30, "Defined Benefits Plans — Pensions" purposes and comparing our projected benefit obligation to the fair value of plan assets).

If our cash flow from operations is insufficient to fund our worldwide pension obligations, we may be materially and adversely harmed and have to seek additional capital.

The divestiture of Domilens will reduce our sales.

Domilens GmbH, our former German subsidiary, was profitable and provided a significant part of our sales. In 2009, Domilens accounted for $24,286,000, or 32% of our total sales. While sales from STAAR's remaining business generate higher gross profit margins than the sales generated from Domilens, STAAR will have to significantly increase its sales from its core IOL and ICL business, or significantly reduce its expenses, to achieve its target of positive cash flow in 2010. If STAAR does not achieve positive cash flows in 2010, it may need to seek additional sources of financing to maintain operations.

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

We have accumulated approximately $120.9 million of federal net operating loss carryforwards as of January 1, 2010 to be used in future quarters 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 2029.

FDA compliance issues have delayed approvals 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 regularly scheduled inspections of the Nidau, Switzerland facility between June 2 and June 5, 2009 and of the Monrovia, California facility, between February 23 and March 4, 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 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 integrity hold on the TICL application. On July 21, 2009, the FDA indicated that it was satisfied with corrective actions taken by STAAR to resolve these deficiencies, and removed the integrity hold.

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 to continue to devote 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 considerably 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 completed specified actions to satisfy FDA concerns regarding deficiencies in STAAR's oversight of past clinical activities. The integrity hold was removed, and consideration of the application resumed on July 21, 2009. On February 3, 2010, STAAR received a letter of deficiency from the FDA outlining additional questions and requesting labeling changes related to the TICL application. The letter provides that STAAR has 180 days to present its response to the FDA. STAAR cannot predict when or if the Toric ICL may be approved.

Continued effects of the global recession could reduce sales of our refractive products.

The global economy has been affected by a severe 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. Despite indications that the U.S. economy has resumed growth, employment, consumer spending and consumer confidence have not recovered to pre-recession levels in the U.S. Many regions of the world remain severely affected, including Spain, which has been a significant market for the ICL and TICL.

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 globally. STAAR believes that seven of the top ten refractive markets experienced a decline in total refractive procedures during 2009. The U.S. market, where we believe procedures have declined to approximately 50% of their level two years ago, appears to be the worst affected. Visian ICL sales have not been as badly affected, and grew worldwide in 2009. If the economic recovery does become stronger, or if the global economy falls back into recession, Visian ICL sales could continue to grow slowly or decline. Because the Visian ICL is STAAR's fastest growing and highest gross margin product, restricted growth or a decline in its sales could materially harm STAAR's business.

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 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, in part, been a factor in the steep decline in demand for such procedures during 2008 and 2009. 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.

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 then 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 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 and Japan drops dramatically in July and August, and these 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, Abbot Medical Optics and Bausch & Lomb have much greater financial resources than we do and some of them have large international markets for a full suite of ophthalmic products. Their greater resources for research, development and marketing, and their greater capacity to offer comprehensive products and equipment to providers, make it difficult for us to compete. We have lost significant market share to some of our competitors.

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 1, 2010, sales from international operations were 79% 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 Japanese Yen, Euro, and the Swiss Franc. 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, 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 increased after we completed the acquisition of STAAR Japan Inc., and, notwithstanding the March 2, 2010 sale of Domilens, our German distribution subsidiary, these risks remain significant. The risk that unauthorized conduct may go undetected will always be greater in foreign subsidiaries.

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.

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

We spent about 8% of our sales on research and development during the fiscal year ended January 1, 2010, and we expect to spend approximately 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. Future cost cutting initiatives could result in unexpected reductions in the reimbursement rates for IOLs and related products. In some countries government insurers have sought to control costs by limiting the total number of procedures they will reimburse. The U.S. Congress is currently considering 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 worldwide, which increases our costs and could prevent us from selling our products.

STAAR is regulated by regional, national, state and local agencies. In the U.S our regulators include 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 subject to similar regulatory regimes in other key regions of Europe and Asia, in particular Japan. Regulations worldwide are becoming more stringent. We have described in detail the regulations governing approval of medical devices and their manufacturing in the “Business – Regulatory Matters” section of this Report. 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.

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 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. Generally, 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. Key patents covering the Collamer formulation and essential design features of the Visian ICL and TICL will expire between 2014 and 2016. 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 the following:

- stockholders have limited ability to remove directors;
- stockholders cannot act by written consent;
- stockholders cannot call a special meeting of stockholders; and
- stockholders must give advance notice to nominate directors.

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

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

Future sales of our common stock could reduce our stock price.

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

The market price of our common stock is likely to be volatile.

Our stock price has fluctuated widely, ranging from $0.79 to $4.26 per share during the year ended January 1, 2010 and was $3.63 on March 9, 2010. Our stock price could continue to experience significant fluctuations in response to factors such as market perceptions, quarterly variations in operating results, operating results that vary from the expectations of securities analysts and investors, changes in financial estimates, changes in market valuations of competitors, announcements by us or our competitors of a material nature, additions or departures of key personnel, future sales of Common Stock and stock volume fluctuations. Also, general political and economic conditions such as recession or interest rate fluctuations may adversely affect the market price of our stock.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

Our operations are conducted in leased facilities throughout the world. Our executive offices, manufacturing, warehouse and distribution, and primary research facilities are located in Monrovia, California. STAAR Surgical AG maintains office, manufacturing, and warehouse and distribution facilities in Nidau, Switzerland. The Company has one additional facility in Aliso Viejo, California for raw material production and research and development activities. STAAR Japan maintains executive offices and distribution facilities in Shin-Urayasu, Japan and a manufacturing and R&D facility in Ichikawa City, Japan. The Company leases an additional sales and distribution facility in Australia. We believe our manufacturing facilities in the U.S., Switzerland and Japan are suitable and adequate for our current and future planned requirements. The Company could increase capacity by adding additional shifts at our existing facilities.

Item 3. Legal Proceedings

Two lawsuits against STAAR, Parallax Medical Systems v. STAAR Surgical Company (California Superior Court, County of Orange, Case No. 07CC10136) and Moody v. STAAR Surgical Company; (California Superior Court, County of Orange, Case No. 07CC10132) were settled on March 30, 2010. On that date STAAR and all other parties to the matters entered into a Stipulation for Settlement that globally resolves all pending disputes among them. This settlement satisfies in full the $4.9 million judgment against STAAR in the Parallax matter and the $6.5 million judgment against STAAR in the Moody matter. In exchange for complete mutual releases, the Stipulation provides for payment by STAAR of $4 million as its contribution to the global settlement. STAAR's contribution will be paid from the $7.4 million restricted deposit that STAAR placed with the Court on June 22, 2009. The balance of those funds, approximately $3.4 million, will be returned to STAAR. In connection with the settlement, STAAR will voluntarily dismiss its appeals in both cases. The cases are described in greater detail below.

The Parallax Case.

The California Superior Court, County of Orange, rendered final judgment in the Parallax case on May 11, 2009, in accordance with a March 2, 2009 jury verdict finding that STAAR was liable for approximately $2.2 million in actual damages and $2.7 million in punitive damages to Parallax Medical Systems, Inc. for intentional and negligent interference with prospective business advantage. Parallax is a former independent regional manufacturer's representative ("RMR") of STAAR. Parallax promoted sales of STAAR products in the southeastern region of the U.S. under a contract that expired on July 31, 2007. The jury found that STAAR had interfered with Parallax's prospective economic advantage when it informed a regional IOL distributor that Parallax had a covenant restricting the sale of competing products. On July 14, 2009, the Court in part granted STAAR's motion to strike or reduce Parallax's claim for approximately $109,000 in trial-related costs, of which approximately $56,000 was awarded to Parallax. On August 18, 2009, the Court amended its final judgment to include these costs and approximately $20,000 in pre-judgment interest, for a total judgment of $4,966,000.

On October 22, 2009, STAAR's general liability insurer agreed to pay a portion of the legal fees incurred by STAAR after July 1, 2009 for the appeal in the Parallax case. The insurer's agreement to defend was subject to a full reservation of its rights and defenses.

STAAR filed notice of appeal of the Parallax judgment, and on June 22, 2009, deposited $7.3 million into a restricted account with the Court to assure payment of the judgment, thereby staying any enforcement of the judgment pending the appeal. The deposit account bears interest, and as of the date of this Report the account balance is approximately $7.4 million. STAAR filed its appellate Opening Brief on January 22, 2010. Pursuant to the March 30, 2010 global settlement of the Parallax and Moody matters STAAR will voluntarily dismiss its appeal of the Parallax judgment; $4 million of the funds deposited with the Court will be disbursed as directed by counsel for the Parallax and Moody plaintiffs. The balance of approximately $3.4 million will be refunded to STAAR.

The Moody Case

The California Superior Court, County of Orange, rendered judgment in the Moody case against STAAR on December 8, 2009 in accordance with a December 1, 2009 jury verdict finding that STAAR was liable for $4 million in actual damages and $2.5 million in punitive damages to Scott C. Moody, Inc. ("SMI") for intentional and negligent interference with prospective business advantage. SMI, also a former RMR of STAAR, filed a complaint against STAAR on the same day that Parallax filed its complaint. Moody promoted sales of STAAR products in the southwestern region of the U.S., under a contract that, like Parallax's, expired on July 31, 2007. The jury found that STAAR had interfered with SMI's prospective economic advantage when it informed a regional IOL distributor that SMI had a covenant restricting the sale of competing products. Notice of judgment on post-trial motions in the case was served on February 8, 2010. In post-trial motions the court granted the plaintiff's motions for costs of $24,842 and for approximately $130,000 in legal fees and other assessments that STAAR has already paid separately from the funds to be contributed to the March 30, 2010 global settlement.

On October 14, 2009, STAAR's general liability insurer agreed to pay a portion of the legal fees incurred by STAAR after July 1, 2009 for its defense of the Moody case. The insurer's agreement to defend was subject to a full reservation of its rights and defenses.

On January 29, 2010, attorneys representing STAAR and SMI signed a stipulation extending the date for potential enforcement and execution of the $6.5 million Moody judgment to April 30, 2010. The purpose of the extension was to allow the parties involved, including certain insurers, to attempt to negotiate a global settlement, along with the Parallax matter, in a mediation that took place on March 29-30, 2010, and to avoid the necessity of STAAR posting an appeal bond during the term of the stipulation.

STAAR filed notice of its appeal of the Moody judgment on March 8, 2010. Pursuant to the March 30, 2010 global settlement of the Parallax and Moody matters STAAR will voluntarily dismiss its appeal of the Moody judgment.

From time to time the Company is subject to various claims and legal proceedings arising out of the normal course of our business. These claims and legal proceedings relate to contractual rights and obligations, employment matters, and claims of product liability. STAAR maintains insurance coverage for product liability claims. While the Company does not believe that any of the claims known is likely to have a material adverse effect on its financial condition or results of operations, new claims or unexpected results of existing claims could lead to significant financial harm.

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

There were no matters submitted to a vote of security holders during the quarter ended January 1, 2010.

PART II

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

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

Period	High	Low
2009		
Fourth Quarter	$ 4.24	$ 2.47
Third Quarter	4.26	1.90
Second Quarter	3.44	0.79

First Quarter	2.78	0.80
2008		
Fourth Quarter	$ 4.71	$ 1.16
Third Quarter	5.98	2.98
Second Quarter	3.89	2.23
First Quarter	2.68	2.00

On March 9, 2010, the closing price of the Company's Common Stock was $3.63 per share. Stockholders are urged to obtain current market quotations for the Common Stock.

As of March 11, 2010, there were approximately 504 record holders of our Common Stock.

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

As of March 10, 2010, options to purchase 3,145,281 shares of Common Stock were exercisable.

Stock Performance Graph

The following graph compares the yearly and cumulative return on an investment in STAAR's common stock over the last five fiscal years to the yearly and cumulative return of the following over the same time period: (1) the composite of all United States and foreign companies listed on the Nasdaq Stock Market (the "Nasdaq Index"); and (2) the composite of all United States and foreign companies listed on the Nasdaq Stock Market that operate in the surgical, medical and dental instrument and supply industries (the "Peer Index"), based on Standard Industrial Classification ("SIC") codes in the range of 3840 through 3849. The Company's SIC code is 3845. The comparison assumes $100 was invested on December 31, 2004 in STAAR's common stock and in each of those indices, and that dividends were reinvested. The Center for Research in Security Prices of the University of Chicago's Graduate School of Business compiled the Peer Index and produced the graph. The stock price performance on the following graph is not necessarily indicative of future stock price performance.

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

CRSP Total Returns Index for:	12/2004	12/2005	12/2006	12/2007	1/2009	1/2010
STAAR SURGICAL CO	100.0	126.00	111.82	42.11	37.97	49.44
Nasdaq Stock Market (US & Foreign)	100.0	102.27	112.80	124.68	59.76	86.89
NASDAQ Stocks (SIC 3840 – 3849 US + Foreign) Surgical, Medical, and Dental Instruments and Supplies	100.0	109.81	115.73	147.16	79.25	115.55

Notes:

A. The lines represent monthly index levels derived from compounded daily returns that include all dividends.

B. The indexes are reweighted daily, using the market capitalization on the previous trading day.

C. If the monthly interval, based on the fiscal year-end, is not a trading day, the preceding trading day is used.

D. The index level for all series was set to $100.0 on December 31, 2004.

Item 6. Selected Financial Data

The following table sets forth selected consolidated financial data with respect to the five most recent fiscal years ended January 1, 2010, January 2, 2009, December 28, 2007, December 29, 2006 and December 30, 2005. The selected consolidated statement of operations data set forth below for each of the three most recent fiscal years, and the selected consolidated balance sheet data set forth below at January 1, 2010 and January 2, 2009, are derived from our consolidated financial statements, which have been audited by BDO Seidman, LLP, independent registered public accounting firm, whose report is included in this Form 10-K. The selected consolidated statement of operations data set forth below for each of the two fiscal years in the periods ended December 29, 2006 and December 30, 2005, and the consolidated balance sheet data set forth below at December 28, 2007, December 29, 2006 and December 30, 2005 are derived from audited consolidated financial statements of the Company not included in this Annual Report. The selected consolidated financial data should be read in conjunction with the consolidated financial statements of the Company, and the Notes thereto, included in this Annual Report, and "Management's Discussion and Analysis of Financial Condition and Results of Operations" in Item 7.

	Fiscal Year Ended				
	January 1, 2010	January 2, 2009	December 28, 2007	December 29, 2006	December 30, 2005
	(In thousands except per share data)				
Statement of Operations					
Net sales	$ 75,345	$ 74,894	$ 59,363	$ 56,951	$ 51,303
Cost of sales	33,452	34,787	30,097	30,801	27,517
Gross profit	41,893	40,107	29,266	26,150	23,786
Selling, general and administrative expenses					
General and administrative	15,710	15,730	12,951	10,891	9,727
Marketing and selling	24,257	27,053	23,723	22,112	18,552
Research and development	5,893	7,938	6,711	7,080	5,573
Other operating expenses (recovery), net	(238)	9,773	—	(331)	746
Total selling, general and administrative expenses	45,622	60,494	43,385	39,752	34,598
Operating loss	(3,729)	(20,387)	(14,119)	(13,602)	(10,812)
Total other (expense) income, net	(979)	(1,285)	(1,037)	95	854
Loss before income taxes and non-controlling interest	(4,708)	(21,672)	(15,156)	(13,507)	(9,958)
Income tax provision	1,492	1,523	843	1,537	1,239
Non-controlling interest	—	—	—	—	(22)
Net loss	$ (6,200)	$ (23,195)	$ (15,999)	$ (15,044)	$ (11,175)
Basic and diluted net loss per share	$ (0.19)	$ (0.79)	$ (0.57)	$ (0.60)	$ (0.47)
Weighted average number of basic and diluted shares	32,498	29,474	28,121	25,227	23,704
Balance Sheet Data					
Working capital	$ 13,466	$ 10,807	$ 21,006	$ 14,363	$ 22,735
Total assets	58,681	52,582	54,179	47,770	52,755
Notes payable, net of discount	—*	4,414	4,166	1,802	1,676
Other long-term liabilities	3,887	3,910	2,500	1,079	854
Stockholders' equity	21,070	16,027	36,225	31,760	40,366

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* included in current liabilities

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

The matters addressed in Management's Discussion and Analysis of Financial Condition and Results of Operations that are not historical information constitute "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Readers can recognize forward-looking statements by the use of words like "anticipate," "estimate," "expect," "project," "intend," "plan "believe," "will," "target," "forecast" and similar expressions in connection with any discussion of future operating or financial performance. In particular, these include statements relating to future actions, prospective products or product approvals, future performance or results of current and anticipated products, sales efforts, expenses, interest rates, foreign exchange rates, the outcome of contingencies, such as legal proceedings, and financial results.

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

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

Overview

Strategy

Performance Against 2009 Key Operational Metrics

During 2009, STAAR focused on the following key operational metrics:

- to improve cash flow from operations;
- to increase gross profit margin;
- to continue cost reduction efforts;
- to secure key regulatory approvals;
- to increase the ICL's share of the refractive market in key territories.

Achievement against these goals is discussed below.

Improve cash flow from operations. For several years prior to 2009 STAAR had not generated enough cash to sustain its operations. STAAR has steadily reduced its use of cash significantly in recent quarters primarily through cost reductions, and in the second quarter of 2009 generated $286,000 in cash from operations, its first positive cash flow from operations after six consecutive negative years. In the fourth quarter of 2009 STAAR generated $1,125,000 in cash from operating activities, compared to $991,000 used for operating activities in the fourth quarter of 2008. During fiscal year 2009 STAAR generated $1.4 million in cash from operating activities, compared to $8.2 million in cash used for operating activities in 2008.

Improving cash flow and achieving profitability remain key goals of STAAR during 2010. The sale of Domilens in the first quarter of 2010 will present a challenge in meeting these goals, because Domilens has historically been profitable and generated cash for STAAR. STAAR's objectives for earnings growth and continued positive cash flow, and risks related to their achievement, are discussed in detail below under "2010 Operational Goals."

STAAR exited 2009 with cash, cash equivalents, and restricted cash of $13.7 million, compared with $5.2 million at January 2, 2009. STAAR's cash position was enhanced by the $8.5 million net cash proceeds of a registered direct offering of common stock completed on June 17, 2009. STAAR also received approximately $12.5 million in net cash proceeds from the sale of Domilens in the first quarter of 2010. The adequacy of cash we expect to generate from operations in 2010, along with the recently obtained capital, to satisfy STAAR's needs is discussed below under "Liquidity and Capital Resources"

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During fiscal year 2008 and 2009 STAAR's cash flow has been significantly affected by the cost of defending the Parallax and Moody lawsuits. Both lawsuits were settled on March 30, 2009. As a result, STAAR expects its legal costs to be approximately $1.5 million lower in 2010 than in 2009.

Increase gross profit margins. In recent quarters STAAR has generally experienced increased sales in ICL and IOL sales. While growth in sales remains an important goal, STAAR believes that the key to achieving sustainable profitability is to increase its gross profit margins. Despite a number of initiatives to improve gross profit margins, STAAR's gross profit margin for 2009 was 55.6%, up 200 basis points only because 2008 gross profit margins of 53.6% were negatively impacted by $1.5 million in purchase accounting charges recorded in the first quarter of 2008 related to the acquisition of STAAR Japan.

Several initiatives of STAAR helped gross profit margins in 2009, in particular increased worldwide sales of ICLs and TICLs, increased average selling prices of IOLs in the U.S., and de-emphasis on selling non-lens products. However, a number of unexpected challenges offset these improvements: reduced manufacturing yields; decreased average selling prices of IOLs and ICLs outside the U.S., and increased cost of goods in Germany, primarily as a result of changes in exchange rates. Decreased average selling prices for IOLs primarily resulted from unusually strong price competition in Japan. Decreased average selling prices for ICLs and TICLs primarily resulted from a pricing concession we made to our Korean distributor to enable the distributor to invest in intensified marketing efforts. We believe we have addressed most of the issues negatively impacting gross profit margins and that those efforts resulted in higher gross profit margins in the fourth quarter of 2009 compared with the third quarter of 2009.

The March 2, 2010 sale of Domilens GmbH is expected to significantly improve STAAR's gross profit margins. This and other initiatives to improve gross profit margin in 2010 are discussed below under "2010 Operational Goals."

Continue Cost Reduction Efforts. Achieving greater operating and administrative efficiency through reduced costs has been a key goal of STAAR, and is a significant element in achieving our goal of profitability. In particular, while STAAR's international operations have generally generated cash or have been cash flow neutral in recent quarters, losses from U.S. operations have been the principal cause of cash use and losses on a consolidated basis. During 2009 STAAR continued cost reduction initiatives that began in the fourth quarter of 2007, yielding a combined reduction in marketing and selling and research and development expenses of $4.8 million in 2009 compared to 2008. This included the following:

- a 10.3% reduction in marketing and selling expense year-over-year, from $27.1 million to $24.3 million, principally as a result of decrease salaries, travel, consulting, promotional activities and commissions in the U.S; and

- a 25.8% reduction R&D expenses year-over-year, from $7.9 million to $5.9 million, principally as a result of decreased salaries, reduced consulting fees and general cost containment.

STAAR believes that the global settlement of the Parallax and Moody litigation on March 30, 2010 will eliminate much of the litigation defense expense that STAAR experienced in 2008 and result in much lower legal expenses in 2010 compared to 2009. Prior to the settlement, the availability of reimbursement for our legal fees from our insurance carrier, along with the transition of the lawsuits from trial to appeal, had already begun to reduce legal defense expense. On October 14, 2009, STAAR's general liability insurer agreed to pay a portion of the legal fees incurred by STAAR after July 1, 2009 for its defense of the Moody case. On October 22, 2009 the insurer agreed to pay a portion of the legal fees incurred by STAAR after July 1, 2009 for the appeal in the Parallax case. STAAR received $780,000 in reimbursement payments related to the Moody case in 2009, and through the date of this report has received $342,000 in 2010. In connection with the global settlement of the Parallax and Moody cases STAAR will voluntarily dismiss its appeals, and except for minor post-settlement matters legal expenditures related to the cases will cease.

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Secure Key Regulatory Approvals. Regulatory approvals of high gross profit margin products in significant markets can yield rapid growth in sales and improvements in profitability. During 2009 the most significant approvals sought by STAAR were for sale of the Visian ICL and TICL in Japan and the TICL in the U.S.

As a result of progress made during 2009, Japan's Ministry of Health, Labor and Welfare (MHLW) approved the sale of the ICL on February, 2, 2010, making it the first phakic IOL approved for the Japanese market. STAAR intends to file a partial change application for approval of the VISIAN Toric ICL, and is currently in discussions with the Pharmaceuticals and Medical Device Agency (PMDA) regarding that process. MHLW generally requires up to one year to fully process a partial change application, although that timeline can change based on the nature of the product under review. Following a two-year process in which STAAR addressed a number of agency concerns, on July 21, 2009, the U.S. Food and Drug Administration ("FDA") notified STAAR that as a result of STAAR's corrective actions the FDA had removed an integrity hold on our application for approval of the TICL, and would resume its consideration of the application. Substantive discussions with the FDA regarding the application resumed at that time. On February 3, 2010 STAAR received a letter of deficiency from the FDA requesting additional analysis of data supporting the safety and effectiveness of the TICL and requesting changes in proposed labeling for the product. STAAR is preparing a comprehensive response to the items in this letter.

Increase the ICL's Share of the Refractive Market in Key Territories. After introducing the ICL in international markets in 1996 STAAR has secured approval for sale in over 40 countries. While sales have increased as new territories were added, we have achieved significant sales and increased share of the refractive surgical market in a select number of territories: in particular, the U.S., Korea, China, India, Spain, Germany, and Latin America. In order to increase ICL sales most effectively, in 2009 STAAR adopted a strategy of focusing on increasing the ICL's share of the refractive market in those territories. Based on growth in STAAR's sales in those countries, and statistics indicating a general decline in the overall refractive market, STAAR believes it succeeded in increasing market share in each of those territories in 2009. The most significant growth took place in the Korean market, where sales reported by STAAR's independent distributor indicate that the Visian products exceeded a 10% share of the overall refractive market. Along with its new opportunity in Japan, STAAR intends to continue to focus its Visian ICL marketing efforts on this group of key markets in 2010.

Key Operational Metrics for 2010

During 2010, STAAR is focused on the following key operational metrics which are designed to enable the company to pursue new growth strategies:

- Double digit growth in sales from core ICL and IOL products;
- Improvement in gross profit margins to the mid-60% level for the year;
- Progress toward profitability throughout the year, with a goal of achieving net income for the full year;

- Continued generation of cash;
- Improve financial condition by retiring obligations and strengthening the balance sheet.

Double digit growth in sales from core ICL and IOL products. To continue generating cash from operations and reach profitability, STAAR must significantly improve sales derived from its higher value products. The sale of Domilens, which has significantly reduced the portion of STAAR's sales derived from lower gross profit margin sales such as third party products, disposables and surgical kits, provides an opportunity for STAAR to focus on its core ICL and IOL products.

STAAR achieved approximately 15% growth in worldwide ICL sales during 2009, and believes similar growth is achievable in 2010, especially with expansion into the Japanese market following the February 2, 2010 approval of the ICL. However, the rate of growth in Visian ICL sales will partly depend on continued improvement in worldwide economic conditions. ICL surgery is a relatively expensive elective procedure and is seldom reimbursed by insurers or government agencies. STAAR believes that that global recession has reduced overall demand for refractive surgery.

STAAR will continue to focus its ICL marketing efforts in the key territories where it has established significant market share, based on the success of this strategy in 2009. Japan will be added to the list in 2010; like other Asian countries, Japan has a high mean rate of myopia, which makes it a promising new market. The key territories in which STAAR will seek to enhance Visian sales during 2010 are the U.S., Japan, Korea, China, India, Spain, Germany, U.K., and France. STAAR believes that the singular success of Visian products in Korea, where STAAR believes it has exceed a 10% penetration rate among all refractive surgical procedures, may provide a model of best practices to increase market share in other key territories.

U.S. military forces currently represent the largest single customer for ICLs in the U.S. Military purchases of ICLs accounted for most of STAAR's 2.5% growth in 2009 U.S. ICL sales over 2008. STAAR does not believe that private sector purchases of ICLs will resume growing significantly until consumer confidence improves, which depends on continued recovery in the U.S. economy.

During 2009 STAAR's international IOL sales increased by 7.6% and U.S. IOL sales decreased by 8.3%. Challenges faced by STAAR in selling IOLs in 2009 included stronger than usual price competition in Japan, where average IOL selling prices are typically higher than in other countries. To maintain gross profit margins of STAAR Japan, STAAR has chosen not to the match deep discounts offered by some competitors, which may limit opportunities to increase Preloaded Injector sales in Japan until economic conditions improve.

STAAR has seen its U.S. IOL sales volume decline steadily for the last several years. However, the rate of decline has recently decreased and STAAR's introduction of aspheric IOLs with NTIOL status in 2008 and 2009 has resulted in higher average selling price for STAAR's IOLs in the U.S., further reducing erosion in sales. STAAR introduced three new products in the U.S. in 2009 to drive growth in its IOL market, the nanoFLEX IOL, the nanoPOINT injection system, and the advanced Epiphany injector for STAAR's three-piece Collamer aspheric lens. These products did not have a significant impact on sales within 2009 due to timing of introduction, but STAAR believes they will have greater impact in 2010, especially the nanoFLEX IOL. STAAR believes its recent product introductions have given the company a very competitive IOL product line with unique features and benefits, and offer an opportunity to regain lost IOL market share. STAAR intends to support these products with sales and marketing growth based initiatives in 2010.

STAAR also expects to obtain FDA approval to sell its silicone Preloaded Injectors in the U.S. during 2010. STAAR believes this product will further enhance its U.S. IOL offering, and will help STAAR maintain or increase its market share in the silicone IOL segment.

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Improvement in gross profit margins to the mid-60% level for the year. As noted above, STAAR did not make the progress it had planned towards increasing gross profit margin in 2009. However, in 2008 STAAR had significantly improved gross profit margin from 49.3% in 2007 to 53.6% in 2008, and STAAR believes it has an opportunity to again increase gross profit margins significantly in 2010. An important factor in this expected improvement is the March 2, 2010 sale of Domilens, which will remove some of the lowest gross profit margin sales from STAAR's product mix: third party products, supplies and disposables like surgical drapes, and assembly of custom surgical kits. STAAR will seek to further increase gross profit margin through the following:

- Increasing ICL sales as a percentage of STAAR's overall product mix. Visian ICLs and TICLs generally yield an 80% gross profit margin. The Visian product line is STAAR's most profitable product family and the largest contributor to enhanced gross profit margins. During 2010 we expect the launch of ICL sales in Japan, and expanding market share in existing markets, to improve STAAR's profitability. The sale of Domilens, whose products were overwhelmingly in the cataract area and included many non-lens products, has significantly increased the portion of our sales derived from the Visian product line.

- Reducing Cost of Preloaded Injectors. In Japan IOLs enjoy higher average selling prices than in most countries, and as a result the Japan IOL business can yield significant gross profit margins and contribute significantly to STAAR's improvement in gross profit margins. However, price competition has recently increased in the Japan IOL market, indicating that STAAR must reduce the cost of producing Preloaded Injectors to sustain or improve IOL gross profit margins in Japan. STAAR believes opportunities exist to further reduce manufacturing costs for its products sold in Japan, which could better enable STAAR to maintain profits in the face of such competition.

- Increase sales of Higher Value IOLs in the U.S. In 2007 and 2008 STAAR began converting its U.S. IOL product offering from lower value legacy products to newer aspheric designs that are eligible for enhanced CMS reimbursement as NTIOLs. With the introduction of the nanoFLEX IOL in 2009, STAAR has introduced aspheric versions for both of its IOL product platforms. As STAAR's customers switch to aspheric lenses, and STAAR sells down its inventories of non-aspheric lenses, U.S. IOL gross profit margins have increased. This process will continue in 2010. In addition, early results of marketing efforts for the nanoFLEX lens suggest that this product may attract new customers to STAAR IOLs and rebuild U.S. IOL market share, further enhancing gross profit margins.

- Continue to Implement Centers of Excellence Program. STAAR believes that it has an opportunity to reduce costs while continuing its history of innovation by rationalizing its business among its worldwide operations through its Centers of Excellence program. During 2009 STAAR moved the production of silicone IOLs for use in Preloaded Injectors from Japan to the U.S., centralizing all silicone lens production in the U.S., thereby reducing STAAR's overall IOL costs. During 2010 STAAR intends to complete the transfer of IOL and ICL injector system manufacturing and R&D from the U.S. to Japan, which is expected to lead to cost savings and a greater focus on STAAR Japan's more advanced lens injector designs. STAAR also intends to take further efforts to improve silicone manufacturing efficiency in the U.S., based in part on the efficiencies of scale made possible by centralized manufacturing.

Progress toward profitability throughout the year, with a goal of achieving net income for the full year. STAAR has reported net losses in each period since 1999. Having achieved positive cash flow from operations in 2009, STAAR is now focused on the goal of delivering net income for fiscal year 2010. Achieving this goal will require further reductions in STAAR's expenses and success in the initiatives to improve profitability contained in our other 2010 objectives.

Continued generation of cash flow from operations. STAAR achieved positive cash flow from operations in 2009, and intends to continue its initiatives to improve cash flow in 2010. To be successful, cash previously generated by Domilens, which accounted for $1.8 million of STAAR's cash from operations in 2009, will need to be replaced with

increased cash from STAAR's remaining operations, although it is anticipated that reduced legal fees should offset a significant portion of the lost cash flow from Domilens. STAAR has been especially challenged to meet its cash flow goals in the first quarter. The first quarter of each fiscal year tends to have the lowest cash flow of the year because of accounting fees related to the annual audit of our financial statements, professional fees for our consultant on internal controls pursuant to the Sarbanes-Oxley Act of 2002, and holiday closures of facilities during December that reduce the processing and payment of invoices by STAAR during the last weeks of the fourth quarter, resulting in a significant increase in cash payments by STAAR as it catches up during the first month of the first quarter.

Improve financial condition by retiring obligations and strengthening the balance sheet. Although the $12.5 million in cash raised from the sale of Domilens significantly improved the cash position of the Company, as discussed below under “Liquidity and Capital Resources,” some of the cash may be needed to meet current financial obligations in 2010 as follows:

- repayment of the $5 million principal balance on the Broadwood Note due on December 14, 2010;
- the right of the holders of 1.7 million shares of our Series A Convertible Preferred stock to redeem them at $4 per share or $6.8 million in aggregate beginning on December 29, 2010.

STAAR’s goal is resolve all of its major obligations with existing capital reserves and cash generated from operations. It also seeks to reserve any future capital raising efforts for initiatives to expand its business, rather than meeting existing obligations. Nevertheless, depending on STAAR’s cash position during the remainder of 2010, it may find it necessary to seek additional financing. See “Financing Strategy” below.

Other Highlights

Divestiture of Domilens.

On March 2, 2010 we completed the divestiture of all of our interest in our former German distribution subsidiary, Domilens GmbH through a management buyout led by funds managed by Hamburg-based Small Cap Buyout Specialist BPE Unternehmensbeteiligungen GmbH (“BPE”). STAAR’s financial advisor in the transaction was Berenberg Bank, a German investment bank headquartered in Hamburg.

The decision to divest Domilens resulted primarily from a need to raise working capital.

STAAR originally purchased Domilens in a series of stock purchases from the founder of the business between 1998 and 2003. STAAR originally intended to use Domilens as a channel for increased sales in the German market. However, by 2009 sales of STAAR product accounted for only approximately 7.6% of Domilens sales. The majority of Domilens sales have been third party products, including IOLs of other manufacturers, disposables and other supplies such as surgical drapes, and the assembly of custom surgical kits containing a package of mostly third party products needed for a single procedure. While profitable, this business operates at gross profit margins that are significantly lower than STAAR’s overall average.

A distribution agreement between STAAR and Domilens provides that Domilens will continue to purchase STAAR products at the unit sales volume previously projected for 2010 through 2012. Because of the nature of the Domilens business and the promise of continued distribution in Germany and Austria at projected levels, STAAR determined that the sale of Domilens would not impede its core business, and would permit management to focus on higher value core business of developing, manufacturing and selling its own advanced ophthalmic products.

STAAR also determined that the gross purchase price for Domilens, at approximately 6.9 times Domilens' earnings before income taxes, represented a reasonable value for its investment in Domilens, and that these funds were of greater use to STAAR as working capital. The Stock Purchase Agreement provides for a Purchase Price of €10,512,100 (approximately $14.3 million at currently prevailing exchange rates). After adjusting for €800,000 in cash dividends received by STAAR from Domilens in December 2009 and January 2010, and the exclusion of expenses related to compliance with the Sarbanes-Oxley Act of 2002, at closing on March 2, 2010 Domilens Akquisitions paid a cash Net Purchase Price of €9,685,700 (approximately $13.2 million at currently prevailing exchange rates). €100,000 of the Net Purchase Price was paid into an escrow account, to be held against payment of any unaccrued taxes assessed for periods prior to December 31, 2009. Funds remaining after the resolution of such potential liabilities, if any, will be distributed to STAAR from the escrow account, no later than December 31, 2011.

After expenses of €358,000 (~$485,000) related to investment banking fees, and excluding the escrowed funds and any earn-out payments, STAAR received net cash proceeds of approximately €9.2 million from the Transaction (approximately $12.5 million at the Closing Date foreign exchange rate). The Company will pay a $64,000 marketing allowance in 2010 for Domilens to market STAAR's products post the Transaction. Taxes related to the disposition of Domilens were estimated to be insignificant.

Based on the performance of Domilens in fiscal years 2010, 2011 and 2012, STAAR may earn up to an additional €675,000 (approximately $920,000 at currently prevailing exchange rates). These additional "earn-out" payments will be paid on achievement of specified earnings before income tax ("EBIT") as set forth below. If a target is missed in any year, but in the following year Domilens achieves the target and also makes up for the earlier shortfall, the payments for both years will be earned and paid.

Fiscal Year	Domilens EBIT	Earn-Out Payment
2010	€2,500,000 (~ $3.4 million)	€200,000 (~$273,000)
2011	€2,900,000 (~ $3.9 million)	€225,000 (~$307,000)
2012	€3,500,000 (~ $4.7 million)	€250,000 (~$340,000)

The benefits expected to be achieved from the Domilens divestiture include the following: approximately $12.5 million in net cash proceeds; greater focus on STAAR's core business; significantly enhanced gross profit margins; and a contractual commitment to meet projected sales levels for STAAR products in Germany and Austria through 2012.

The earn-out payments will be earned only if Domilens significantly improves its performance over levels it has historically been able to achieve. Domilens may not be able to achieve these improvements. The escrow account will be used to pay any additional unaccrued taxes that the German tax authorities may assess after their next tax audit, which the Company cannot predict and may leave little or no funds in the escrow account remaining for distribution to the Company.

U.S. ICL Sales.

U.S. ICL Sales. We consider ICL sales growth in the U.S. market to be important because of the size of the U.S. refractive surgery market and the perceived worldwide leadership of the U.S. in adopting innovative medical technologies. The Visian ICL was approved by the FDA for treatment of myopia on December 22, 2005.

Visian ICL sales in the U.S. grew by 2.5% during 2009 compared to prior year, and grew 18% in 2008 when compared to 2007 levels. Most of the U.S. growth in ICL sales has been in sales to the military, while most of the private sector suffered similar declines to the overall refractive market in the U.S. Despite these continuing challenges to the LASIK market the Visian ICL has continued to grow market share.

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In order to significantly increase U.S. sales of the ICL, private sector sales must also resume growth. STAAR believes that the continued global recession represents the largest challenge to increased growth in U.S. private sector ICL sales. Refractive surgery is an elective procedure generally not covered by health insurance. Patients must pay for the procedure, frequently through installment financing arrangements. STAAR believes that the lack of growth in private sector ICL sales in the U.S. results from the significantly lower volume of patients seeking refractive surgery in the last two years, which has reduced the number of patients to whom the ICL is offered. While ICL sales have been much more resistant to the recession than laser-based procedures, unless the recent economic recovery continues and consumer spending levels also recover, private sector ICL sales will not grow significantly and may decline. STAAR believes that its share of the U.S. refractive market has grown during the past two years, which will position the ICL for strong sales growth when conditions improve. By contrast, the U.S. refractive market has declined by approximately 50% during the past two years.

The ICL has continued to benefit from positive media coverage during 2009 and early 2010. For example, in February 2010, it was widely reported that Steve Holcomb, who won a gold medal in 2010 Winter Olympics as pilot of the U.S. four-man bobsled team, had been able to continue his successful athletic career only because he had receive ICLs to correct his severe myopia approximately two years ago.

In addition to poor conditions in the general economy and in particular the refractive surgery market, other challenges to sustained growth in U.S. Visian ICL sales include the following:

- the U.S. refractive surgery market has been dominated by corneal laser-based techniques, which continue to be better known than the Visian ICL among potential refractive patients;

- other newly introduced surgical products will continue to compete with the Visian ICL for the attention of surgeons seeking to add new, high value surgical products, in particular multifocal and accommodating IOLs;

- negative publicity about complications of LASIK could reduce interest in all refractive surgical procedures; and

- FDA approval of the TICL, which STAAR sells in international markets for treating patients affected by both myopia and astigmatism, has been delayed.

On April 25, 2008, the FDA Ophthalmic Devices Panel held a public meeting to discuss issues of medical complications and customer satisfaction following refractive surgery. While the panel also discussed phakic IOLs such as the Visian ICL, most of its discussions centered on LASIK and testimony regarding customer dissatisfaction following LASIK surgery. The Panel recommended enhanced patient warnings of possible complications for LASIK and created a task force to study methods of better identifying those patients who are more likely to have an unsatisfactory outcome from laser vision correction. On October 15, 2009, the FDA announced a three-phase collaborative study on the potential impact of LASIK surgery on a patient’s quality of life, and also issued warning letters to seventeen ambulatory surgery centers citing inadequate systems for reporting adverse events resulting from LASIK. These FDA activities have been widely reported in the U.S. While it is difficult to assess precisely the impact that the FDA’s increased scrutiny on LASIK has had on patient attitudes or the recommendations of practicing surgeons, it is possible that reduced demand for laser eye surgery observed in 2008 and 2009 was caused in part by concerns regarding complications and potential patient dissatisfaction. Patient concerns about LASIK could increase interest in the Visian ICL as an alternative for patients who have a greater risk of complications from LASIK. The fact that the Visian ICL is removable if a patient is dissatisfied with the outcome may also be appealing to some patients with new concerns about risks of refractive surgery. However, STAAR believes the negative publicity concerning LASIK has decreased patient interest in all refractive surgery, including Visian ICL. 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.

STAAR makes the ICL available to selected surgeons only after completion of a training program that includes proctoring of selected supervised surgeries. STAAR believes that this carefully guided method of product release is essential to help ensure the consistent quality of patient outcomes and the high levels of patient satisfaction needed to establish wide acceptance of the ICL as a primary choice for refractive surgery.

As the U.S. market for ICLs has matured, STAAR has placed less emphasis on increasing its overall customer base and devoting more attention to identifying and supporting those practices that show potential for significant repeat business through a professional commitment to the ICL technology.

Because the refractive surgery market has been dominated by corneal laser-based techniques, STAAR faces special challenges in introducing an intraocular refractive implant. STAAR has developed a number of marketing tools and practice support programs to increase the use of the ICL and awareness of its advantages in refractive surgery centers throughout the U.S. and around the world.

U.S. IOL Sales.

For several years STAAR has experienced a decline in U.S. market share of IOLs. The rate of decline has slowed as STAAR has begun replacing older lens designs with higher priced NTIOL lenses. During 2009 U.S. IOL sales declined 8% compared to rates of decline of 16% 2008 and 20% in 2007. Factors contributing to long-term decline in U.S. IOL sales include the slow pace of product improvement and enhancement during a period when we devoted most of our research and development resources to introducing the ICL and to resolving the regulatory and compliance issues raised by the FDA. This long-term trend was intensified in 2007 by disruption in STAAR's independent sales force when STAAR was unable to reach a new contract with regional manufacturer's representatives in the third quarter of 2007. In addition the trend was exacerbated by STAAR's lagging behind its competitors in the introduction of IOLs with advanced aspheric optics, and by the entry of Alcon as a competitor in the Toric IOL market.

STAAR's strategy to achieve its gross profit margin target in its U.S. IOL business is to rationalize its product offering around its higher value products, including recently introduced products and products planned for introduction in the near future. This has included aspheric optics across all IOL platforms, approval of higher reimbursement from Medicare for these lenses, improved delivery systems for Collamer IOLs to broaden their appeal and preloaded delivery systems for silicone lenses. Successful implementation of this strategy is subject to risks, including the risk of delays in developing new products or securing regulatory approval.

STAAR's initiatives to enhance its IOL product line have resulted in the following recent developments:

- the introduction of STAAR's aspheric three-piece Collamer IOL in April 2007;
- the introduction of STAAR's aspheric three-piece silicone IOL November 2007;
- the April 2008 introduction of the nanoPOINT injector, which delivers STAAR's single-piece Collamer IOL, through a 2.2 mm incision;
- the grant of New Technology IOL ("NTIOL") status for the aspheric three-piece Collamer IOL in March 2008;
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the grant of NTIOL status for the nanoFLEX aspheric single-piece Collamer IOL and the aspheric three-piece silicone IOL in July 2008;

- the introduction of the nanoFLEX aspheric single-piece Collamer IOL in the second quarter of 2009, which brings advanced aspheric optics to the micro-incision nanoPOINT platform; and

- the launch of the Epiphany injector for the Collamer three-piece lens in the third quarter of 2009 which brings smoother and more controlled delivery to one of STAAR's most advanced lenses and paves the way for U.S. introduction of the silicone preloaded injector.

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") will grant 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). This additional reimbursement expires on February 26, 2011 for all IOLs in this class. Because the 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.

All of STAAR's aspheric lenses sold in the U.S. 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.

STAAR intends to continue to focus on the following projects designed to make our IOL product offering more competitive:

- Complete the development of the Collamer Toric IOL to complement our pioneering silicone Toric IOL and better compete with the Alcon acrylic Toric IOL. The Collamer Toric IOL should provide a product with advanced optic materials and rotational stability to provide superior outcomes for cataract patients with astigmatism;

- Gain approval for a preloaded silicone IOL injector system in the U.S. in 2010;

- Develop a preloaded injector system for our Collamer IOLs;

- Initiate a formal post-market clinical evaluation to support a possible submission to the FDA of claims that the lens offers patients less spectacle dependence or accommodation; and

- Initiate a clinical study of a new IOL we have designed to enhance the accommodating properties of Collamer.

STAAR cautions that the successful development and introduction of new products is subject to risks and uncertainties, including the risk of unexpected delays and, in some cases, approval of regulatory authorities.

STAAR's development efforts aim to realize the full market potential for Collamer IOLs by continuously improving lens delivery systems and differentiating STAAR's silicone IOL offering through the Preloaded Injector. Approximately one-half of IOLs sold by STAAR in the U.S. are made of silicone, which was the original material used for foldable IOLs. Physician preferences in the U.S. have shifted to toward acrylic IOLs and silicone IOLs now account for approximately 18% of the U.S. IOL market. STAAR believes that its Collamer lenses have outstanding optical qualities and superior biocompatibility, and should be capable of competing with any of our competitor's acrylic lens products in the advanced material sector. In addition, increasing use of the ICL, which relies on the outstanding optical properties of Collamer, has also introduced the advantages of the Collamer material to a growing number of surgeons. However, growth of the Collamer IOL market has been limited by the difficulty of perfecting delivery systems for the soft Collamer material. Although acrylic lenses do not have the same level of optical performance in the eye as Collamer and often introduce glare or glistening into the visual field, the stiffness and toughness of the acrylic material makes design of delivery systems less difficult. STAAR has completed a number of

development projects in place intended to make Collamer lenses easier to deliver and broaden customer appeal. The nanoPOINT injector system, which delivers the nanoFLEX one-piece Collamer IOL through a 2.2 mm incision, was the first of these projects to reach market and was launched in April 2008. In addition the launch of the Epiphany injector for the Collamer three-piece lens in the third quarter of 2009 brings smoother and more controlled delivery to one of STAAR's most advanced lenses.

Over the past several years surgeons implanting the nanoFLEX IOL have reported that their cataract patients have better than expected near vision. In late 2008, STAAR organized the Collamer Accommodating Study Team or "CAST." The CAST consists of eight prominent physicians across the U.S. who are implanting the recently launched nanoFLEX IOL and are checking both near and intermediate vision approximately one month post operation. Feedback from the group indicates that the near vision achieved is better than that of any conventional IOL where we have comparative data. The feedback also indicates that the intermediate vision is better than "presbyopia correcting" IOLs that have been studied and near vision approaches that of presbyopia correcting IO that are already on the market.

While introduction of the nanoFLEX lens did not result in increased U.S. IOL sales in 2009, STAAR believes that surgeon interest in the product is growing and that it represents a significant opportunity to increase STAAR's U.S. IOL market share. To further pursue this opportunity, in the first quarter of 2010 STAAR initiated a program called the "nanoFLEX challenge" which is intended to facilitate an interested surgeon's evaluation of the visual outcomes for patients receiving nanoFLEX IOLs compared with the outcomes from any other standard IOL currently used by the surgeon.

The 2009 introduction of the Epiphany injector, an advanced system which makes delivery of the three-piece Collamer aspheric IOL more reliable and predictable, has not resulted in increased sales of this advanced lens. Based on surgeon feedback, STAAR has developed an easier loading mechanism for this injector, which it intends to introduce in the first half of 2010. STAAR believes that this lens also has the potential to improve STAAR's market share, particularly among surgeons who prefer loop haptics to the plate haptic design of the nanoFLEX. It plans concerted marketing efforts for the three-piece Collamer aspheric lens once the improved Epiphany injector becomes available.

While the market share of silicone IOLs has been slowly declining overall, a significant number of surgeons continue to select silicone lenses for their patients. Among U.S. IOL sales, STAAR believes that its recently introduced aspheric, three-piece silicone IOL offers outstanding optical performance and with its recently granted NTIOL status could enable STAAR to retain or possibly increase its market share within the silicone IOL sector, especially if STAAR's efforts are successful in securing FDA approval to make it available in a Preloaded Injector.

Reversing the decline in U.S. IOL sales will require STAAR to overcome several short and long-term challenges, including successfully meeting its objectives to develop new and enhanced products, organizing, training and managing a specialized cataract sales force, managing independent local sales representatives, and competing with much larger companies. We cannot assure that this strategy will ultimately be successful.

Medical Device Regulatory Compliance, Clinical Oversight and TICL Approval. As discussed above under the caption "Business — Regulatory Matters," STAAR's ability to develop, manufacture and distribute its products depends heavily on maintaining good standing with the FDA and other regulatory agencies. Based, in part, on the results of the FDA inspections of STAAR's California facilities in 2009 and 2006 and STAAR's Nidau, Switzerland facility in 2009, STAAR believes that it is substantially in compliance with the FDA's Quality System Regulations and Medical Device Reporting regulations. STAAR has invested significant resources in maintaining regulatory compliance and expects to continue to do so in the future.

Financing Strategy

STAAR has reported losses and negative cash flows on a consolidated basis over the last several years, primarily as a result of losses in the U.S. business. During this period STAAR has raised additional funds to support operations through sales of equity and debt securities. As cash flow improved in recent quarters, STAAR has sought to avoid further financings and to operate exclusively on self-generated cash. This strategy was challenged in the first quarter

of 2009, when cash reserves were drawn down to low levels, positive cash flow had not yet been achieved, and the Company suffered an adverse litigation judgment in the amount of approximately $4.9 million. At the time the judgment became final, STAAR did not have adequate cash or cash equivalents either to satisfy the judgment or to deposit $7.3 million with the court to obtain a stay of enforcement of the judgment while the appeal was pending.

On June 17, 2009, the Company completed a registered public offering (the "Offering") with certain existing institutional investors, raising a total of $8.5 million in cash by issuing 4.6 million shares of Company's common stock. The proceeds were primarily applied to posting the required $7.3 million deposit with the Superior Court of California, County of Orange, while the Parallax verdict is on appeal. On June 22, 2009, following the receipt of proceeds from the Offering, STAAR timely posted this deposit with the Court just before the expiration of a temporary stay of enforcement that had been granted by the court.

Avoiding a similar short-term cash shortfall was a principal consideration in STAAR's divestiture of Domilens on March 2, 2010. Among the expected demands on STAAR's capital resources underlying this decision, the most pressing was the $6.5 million verdict rendered in the Moody case, and the potential need to post a $9.8 million appeal bond on or before April 30, 2010. The Domilens divestiture yielded a total of approximately $12.5 million in net cash proceeds to STAAR. The potential need to post an appeal bond was eliminated by the global settlement of the Parallax and Moody cases on March 30, 2010. STAAR's $4 million contribution to the global settlement will be paid from the $7.4 million restricted deposit that STAAR already had placed with the Court on June 22, 2009 in connection with the Parallax case. As a result, STAAR will be able to apply the entire $12.5 million in net cash proceeds from the Domilens sale to working capital, along with approximately $3.4 million that will be refunded to STAAR from the restricted deposit.

Other recent financing activity includes the December 14, 2007 borrowing by STAAR of $5 million from Broadwood Partners, L.P., at an interest rate of 7% per annum, primarily to fund the acquisition of STAAR's remaining interest in the Canon Staar Joint Venture. On April 2, 2009, after preliminary judgment was entered in the Parallax case, Broadwood and the Company entered into a Temporary Waiver Agreement with respect to any event of default that may occur, or may be deemed to have occurred, under the Broadwood note as a result of the judgment. In consideration of the Temporary Waiver Agreement, STAAR agreed to amend the Original Note to grant to Broadwood a security interest in substantially all of STAAR's assets to secure STAAR's obligations under the Original Note. To effectuate this grant of a security interest, as of April 13, 2009, the Company and Broadwood entered into an Amended and Restated Senior Secured Promissory Note and Security Agreement. The Temporary Waiver Agreement had provided that no such default was deemed to have occurred until June 23, 2009, when a temporary stay of judgment expired.

On June 24, 2009, following the posting of the deposit and satisfaction of conditions of the Temporary Waiver, Broadwood and STAAR again amended the Note by replacing the Temporary Waiver with a provision stating that because the Company secured a stay of enforcement of judgment until the completion of the appeal by posting the required deposit with the Court, any default that may have otherwise resulted from the Parallax judgment is cured. Broadwood remained entitled to receive interest at the rate of 20% per annum beginning on June 23, 2009, as would have been applicable in the event a default had occurred under the original terms of the Note. Under the terms of the amended Note, the final resolution of the Parallax and Moody cases results in the interest rate on the loan returning to the 7% pre-default level. Such final resolution occurred on March 30, 2010.

The Broadwood Note prohibits STAAR and its subsidiaries from disposing of any of its assets without prior written consent of Broadwood. On February 23, 2010, Broadwood provided written consent to the sale of all of STAAR's interests in Domilens.

On October 14, 2009, STAAR's general liability insurer agreed to pay a portion of the legal fees incurred by STAAR after July 1, 2009 for its defense of the Moody case. On October 22, 2009 the insurer agreed to pay a portion of the legal fees incurred by STAAR after July 1, 2009 for the appeal in the Parallax case. The insurer's agreement to defend these cases was subject to a full reservation of its rights and defenses. STAAR received $780,000 in reimbursement payments related to the Moody in 2009, and through the date of this report has received $342,000 in 2010. Prior to the March 31, 2010 global settlement of the Parallax and Moody cases, the availability of reimbursement for our legal fees from our insurance carrier, along with the transition of the lawsuits from trial to appeal, began to reduce our legal defense expenses significantly. In connection with the global settlement, STAAR will voluntarily dismiss its appeals, and except for minor post-settlement matters legal expenditures related to the cases will cease.

STAAR's need for working capital, and the terms on which financing may be available, will depend in part on its degree of success in achieving and maintaining positive cash flow and earnings through the strategies described above under the caption "Strategy." STAAR cannot assure that such financing will be available on acceptable terms, if at all, if the need arises.

Results of Operations

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

	Percentage of Net Sales			Percentage Change	
	January 1, 2010	January 2, 2009	December 28, 2007	2009 vs. 2008	2008 vs. 2007
Net sales	100.0%	100.0%	100.0%	0.6%	26.2%
Cost of sales	44.4%	46.4%	50.7%	(3.8)%	15.6%
Gross profit	55.6%	53.6%	49.3%	4.5%	37.0%
General and administrative	20.9%	21.0%	21.8%	(0.1)%	21.5%
Marketing and selling	32.2%	36.1%	40.0%	(10.3)%	14.0%
Research and development	7.8%	10.6%	11.3%	(25.8)%	18.3%
Other operating expenses (recovery), net	(0.3)%	13.1%	—	—*	—*
Operating loss	(5.0)%	(27.2)%	(23.8)%	(81.7)%	44.4%
Total other (expense) income, net	(1.3				