STAAR SURGICAL CO
Form 10-K
March 12, 2013

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K

(Mark One)

þ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 28, 2012
or

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

For the Transition period from to

Commission file number: 0-11634

STAAR SURGICAL COMPANY

(Exact name of registrant as specified in its charter)

Delaware	**95-3797439**
(State or other jurisdiction of incorporation or organization)	*(I.R.S. Employer Identification No.)*

1911 Walker Avenue 91016

Monrovia, California

(Address of principal executive offices)

(626) 303-7902

(Registrant's telephone number, including area code)

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

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

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

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes o No þ

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

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

Indicate by check mark 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 þ No o

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

o Large accelerated filer	þ Accelerated filer	o Non-accelerated filer	o Smaller reporting company

(Do not check if a smaller reporting company)

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant as of June 29, 2012, the last business day of the registrant's most recently completed second fiscal quarter, was approximately $229,315,000 based on the closing price per share of $7.77 of the registrant's Common Stock on that date.

The number of shares outstanding of the registrant's Common Stock as of March 1, 2013 was 36,635,713.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement relating to its 2013 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.

STAAR SURGICAL COMPANY

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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 of future operating or financial performance. STAAR Surgical Company cautions investors and prospective investors that any such forward-looking statements are not guarantees of future performance and involve risks and uncertainties, and that actual results may differ materially from those projected in the forward-looking statements. See "Item 1A. Risk Factors."

Item 1. Business

STAAR Surgical Company designs, develops, manufactures and sells implantable lenses for the eye. We are the leading maker of lenses used worldwide in corrective or "refractive" surgery, and we also make lenses for use in surgery that treat cataracts. All of the lenses we make are foldable, which permits the surgeon to insert them through a small incision during minimally invasive surgery.

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™, Epiphany™, and AquaFlow™ are trademarks or registered trademarks of STAAR in the United States (U.S.) and other countries. Collamer® is the brand name for STAAR's proprietary collagen copolymer lens material.

A glossary explaining many of the technical terms used in this report begins on page 13. The reader may also find it helpful to refer to the discussion of the structure and function of the human eye that begins on page 3.

Operations

STAAR has significant operations globally. Activities outside the U.S. accounted for 81% of our total sales in fiscal year 2012. STAAR sells its products in approximately 60 countries, with direct distribution in the United States, Canada, Japan and Spain, and independent distribution in the remainder of the world.

STAAR maintains manufacturing and administrative facilities in the United States, Switzerland and Japan. While STAAR has initiated a project to consolidate all of its manufacturing to its Monrovia, California facility, its current global 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 intraocular lenses (IOLs), and injector systems for its IOLs and Visian implantable Collamer lenses (ICLs). In 2012, we also commenced manufacturing the ICL and assembling preloaded IOL injectors. STAAR also currently manufactures the raw material for Collamer lenses (both IOLs and ICLs) and the AquaFlow Device (for the treatment of glaucoma) in a facility in Aliso Viejo, California.

- *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 STAAR's ICL products and also manufactures the AquaFlow Device. After consolidating manufacturing in Monrovia, California, STAAR plans to continue to maintain an administrative and distribution facility in Switzerland.

- *Japan*. STAAR operates administrative, manufacturing and distribution facilities in Japan under its wholly owned subsidiary, STAAR Japan Inc. STAAR Japan's administrative facility is located in Shin-Urayasu and its manufacturing and distribution facility is located in Ichikawa City. STAAR currently sterilizes and final packages its preloaded IOL injectors at the Ichikawa City facility. Upon completion of the transfer of manufacturing to Monrovia, California, STAAR plans to continue to maintain administrative and distribution facilities in Japan.

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. Our global manufacturing consolidation plan also exposes us to the risk of unexpected costs and possible supply interruptions. See Item *1A. "Risk Factors —The global nature of our business may result in fluctuations and declines in our sales and profits"; "—The success of our international operations depend on our successfully managing our foreign subsidiaries"; "—Non-compliance with anti-corruption laws could lead to penalties or harm our reputation";"—Our global manufacturing consolidation plan exposes us to risk"; and "—We many not enjoy the expected benefits of our global manufacturing consolidation plan and tax strategies."*

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 pigmented 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 natural 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 in 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. 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, which also contains aqueous humor, 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 generally are 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 refractive disorder that limits a person's ability to see in the near and middle distance range as the natural crystalline lens loses its elasticity, reducing the eye's ability to accommodate or adjust its focus for varying distances.

Financial Information about Segments and Geographic Areas

STAAR's principal products are ICLs and IOLs used in ophthalmic surgery. Because STAAR generates 100% of its sales from the ophthalmic surgical product segment, it 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

In designing our products we have the following goals:

· To improve patient outcomes;

· To minimize patient risk; and

· To simplify ophthalmic procedures or post-operative care for the surgeon and the patient.

Visian ICL (ICLs). Refractive surgery corrects the types of visual disorders that glasses or contact lenses have traditionally treated (myopia, hyperopia, astigmatism and presbyopia). The field of refractive surgery includes both lens-based procedures, using products like our ICL, and laser-based procedures like LASIK. The ICL treats a wide range of refractive errors within commonly known vision disorders such as myopia (nearsightedness), hyperopia (farsightedness) and astigmatism.

The ICL folds for minimally invasive implantation behind the iris and in front of the natural crystalline lens, using techniques similar to those used to implant an IOL during cataract surgery, except that the natural lens remains intact in the eye. 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 surgeon typically implants the ICL using topical anesthesia on an outpatient basis. The patient usually recovers vision within one to 24 hours.

The ICL is the only posterior chamber phakic IOL (PIOL) approved for sale in the U.S., and we believe it is the world’s largest selling phakic IOL. We believe that our leadership in commercializing this technology results from a number of factors, including proprietary design features and the biocompatibility of the patent-protected Collamer material. STAAR believes that the biocompatibility of the Collamer material used for the ICL (and Toric ICL –TICL) is a significant factor in the ability to place this lens safely in the posterior chamber of the eye. Compared to lenses placed in the anterior chamber, we believe that placement in the posterior chamber provides superior optical results and superior cosmetic appearance, and poses less risk of damage to the cornea.

The ICL has been implanted into more than 300,000 eyes worldwide. The FDA approved the ICL for myopia for use in the U.S. in December 2005. In September 2011, STAAR launched the ICL with CentraFLOW™ technology, which uses a proprietary port in the center of the ICL optic. The port is of a size intended to optimize the flow of fluid within the eye without affecting the quality of vision, and eliminates the need for the surgeon to perform a YAG peripheral iridotomy procedure days before the ICL implant or a surgical iridotomy at time of implant. By simplifying the procedure and increasing patient comfort, the CentraFLOW™ technology makes the superior visual outcomes of the ICL available through a surgical implantation experience closer to LASIK. Outside the U.S., countries where we may sell the ICL and the Toric ICL (TICL), which corrects for both astigmatism and myopia, include the following: the countries that require the European Union CE Mark, China, Canada, Korea, Japan, India, Brazil, the Middle East and Singapore. We sell the ICL with CentraFLOW™ technology in countries that require the European Union CE Mark and certain countries in the Middle East. STAAR submitted its application for U.S. approval of the TICL to the FDA in 2006 and the ICL with CentraFLOW™ technology in 2012, and they are 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 Canada.

The ICL is available for myopia in the United States in four lengths and 27 powers for each length. Outside the U.S., the ICL is available for myopia and hyperopia and is available in multiple models and lengths in a total of 732 inventoried lenses. This requires us to carry a significant amount of inventory to meet the customer preference for rapid delivery. Outside the U.S. the Toric ICL is available for myopia and hyperopia in the same powers and lengths and also carries additional parameters of cylinder and axis. As a result, we often make the Toric ICL to order, though we were still able to deliver approximately 73% of our Toric ICLs from stock during 2012.

Sales of ICLs (including TICLs) accounted for approximately 55% of our total sales in fiscal 2012, 51% of our total sales in fiscal 2011, and 44% of our total sales in fiscal 2010.

Minimally Invasive Intraocular Lenses (IOLs). We produce and market a line of foldable IOLs for use in minimally invasive cataract surgical procedures. Because these lenses fold, surgeons can implant them 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 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 government agencies reimburse the cost of cataract surgery and IOLs. Some countries have begun to permit ophthalmic surgeons and surgical centers to collect an additional fee from the cataract patient for products and services that go beyond standard treatment. STAAR's strategic direction is to offer IOLs that fall within the categories that offer an opportunity to increase average selling prices. For example, the U.S. Center for Medicare and Medicaid Services (CMS) reimburses certain "premium" lenses at the standard rate of approximately $150, but allows the provider to receive an additional payment from the patient for the premium lens and associated services. STAAR's Toric IOL falls in this category.

Currently, our foldable IOLs are manufactured from both our proprietary Collamer material and silicone. STAAR offers both materials in two differently configured styles: the single-piece design where both the optic and haptics are made of the same material and the three-piece design where Polyimide™ loop haptics are attached to the optic. We believe that the physical and optical properties of Collamer, which contains the highest water content of any material in the market, gives it distinct advantages as a material for prosthetic IOLs used in cataract surgery. The selection of one style over the other is primarily based on the preference of the ophthalmologist. STAAR also sells aspheric IOLs made of silicone and Collamer, which use optical designs that produce a clearer image than traditional spherical lenses, especially in low light. During 2009, STAAR introduced the nanoFLEX IOL, which has a single piece Collamer aspheric optic and can be delivered through a 2.2 mm micro-incision using STAAR's 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.

Also, in Japan, Europe and China, we sell a "Preloaded Injector" with 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. The acrylic-lens-based Preloaded Injector uses a lens supplied by a third party. The supplier also assembles and sells the acrylic Preloaded Injector under its own brand, using injector parts purchased from our subsidiary, STAAR Japan. STAAR Japan's agreement with the supplier 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 41% of our total sales in fiscal 2012, 44% of our total sales in fiscal 2011, and 50% of our total sales in fiscal 2010.

Other Surgical Products

We also sell other related instruments and devices that we manufacture or that are manufactured by others, but we have deemphasized these products in the past few years due to their relatively lower overall gross profit margins. For example, in 2012 we exited the surgical pack business. Sales of other surgical products accounted for approximately 4% of our total sales in fiscal 2012, 5% of our total sales in fiscal 2011, and 6 % of our total sales in fiscal 2010.

Sources and Availability of Raw Materials

STAAR uses a wide range of raw materials in the production of its products. STAAR purchases most of the raw materials and components 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 or materials and are available from a variety of sources although we do not typically pursue regulatory and quality certification of multiple sources of supply. Due to the production capacity constraints with our third party supplier of acrylic IOLs, we are backlogged for those products. We are seeking alternative suppliers.

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, copyrights, and trade secrets. We own or have rights to a number of patents, licenses, trademarks, copyrights, trade secrets and other intellectual property directly related and important to our business. As of December 28, 2012, we owned approximately 113 United States and foreign patents and had approximately 7 patent applications pending. In addition, as of December 28, 2012, our Japanese subsidiary owned approximately 72 Japanese and foreign patents and had approximately 21 patent applications pending.

We consider our patents to be significant when they protect the exclusivity of our material products in the marketplace or provide an opportunity to obtain material royalties or cross-licenses of intellectual property from other manufacturers. Because we have limited knowledge of the research and development efforts and strategic plans of our competitors, we can only estimate the value of our patents and the significance of any particular patent’s expiration. Competitors may be able to design products that avoid infringing on patents that we regard as valuable, or they may find patents that we regard as less significant to be obstacles to their development of competing products. Our internal assessments of our patents include confidential information, the disclosure of which would cause significant competitive harm to STAAR.

Our 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, both stand-alone and preloaded, used with ICLs and IOLs).

STAAR has several patents covering design features that we believe are essential to the safety and effectiveness of its ICLs, and that we believe would be necessary or desirable for any competing posterior chamber phakic IOL. These patents expire between 2014 and 2016. 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 formulation and manufacturing methods for Collamer expire between 2014 and 2016, with the last blocking patent expiring in 2017. Over the past year, we filed patent applications covering new lens designs, and new lens delivery systems.

STAAR also 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, the remaining select group of these patents covering the more fundamental lens delivery technologies will expire between 2013 and 2014.

Trademarks

Worldwide, we sell all of our major products 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.

Confidentiality Agreements

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

Seasonality does not materially affect our sales.

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.

We sell our products directly through our own sales representatives in the U.S., Canada, Japan and Spain and, supplemented by independent distributors, in approximately 60 countries worldwide. We maintain a global marketing team, as well as regional marketing personnel to support the promotion and sale of our products. The global marketing department supports selling efforts by developing and providing promotional materials, educational courses, speakers' programs, participation in trade shows and technical presentations. Where we distribute products directly, we rely on local sales representatives to help generate sales by promoting and demonstrating our products with physicians. In the U.S., we also rely on independent sales representatives to sell our products under the supervision of directly employed sales managers. In Japan, we also sell through a local distributor.

A single customer, WooJeon Medical Co., Ltd., our Korean distributor, has accounted for more than 10% of our consolidated net revenue in each of the last three fiscal years. WooJeon generated the following amounts and percentages of revenue in those years:

Revenue Generated by WooJeon

Fiscal Year	Net Revenue ($, in thousands)	Net Revenue as Percentage of Consolidated Net Revenue	
2012	$ 6,713	10.5	%
2011	$ 8,142	13.0	%
2010	$ 6,080	11.1	%

Backlog

The dollar amount of STAAR's backlog orders is not significant in relation to total annual sales. We generally keep sufficient inventory on hand to ship product when ordered.

The ICL is manufactured to precisely address refractive prescriptions across a broad range of correction, resulting in a large number of Stock Keeping Units (SKUs). The challenge of maintaining inventory in all models can result in a backlog in customer orders. Backlog is not currently at a significant level in relation to our total annual sales. However, unexpectedly large orders for ICLs could increase our backlog. STAAR believes it has sufficient capacity to ramp up production levels to meet demand and that any backlogs will be temporary. However, delays in filling orders can result in lost sales if alternative refractive treatments are available to the patient. Because Toric ICLs treat an even greater variety of refractive errors and at times must be custom made for the patient, customers are accustomed to a special order procedure and do not expect immediate delivery of Toric ICLs from inventory.

Our pre-loaded single piece acrylic IOL has experienced backlogs due to manufacturing capacity constraints occurring at our third-party acrylic lens supplier. Although the supplier is working to resolve the issue, they cannot estimate whether or when their manufacturing capabilities will be able to meet our increasing supply needs. While we are exploring alternatives, there is no guaranty we will identify and validate an alternative supplier.

Government Contracts

No material portion of our business is subject to renegotiation of profits or termination of contracts or subcontracts at the election of the U.S. Government.

Competition

Competition in the ophthalmic surgical product market is intense and is primarily driven by technological innovation and the regulatory approval required to commercialize it in the key markets around the world. The development of new or improved products may make existing products less attractive, reduce them to commodity status or even make them obsolete. To remain competitive, companies such as STAAR must devote continued efforts and significant financial resources to enhance their existing products and to develop new products.

In the refractive market, our ICL technology competes with other elective surgical procedures such as laser vision correction or LASIK, for those consumers who are looking for an alternative to eyeglasses or contact lenses to correct their vision.

We believe our primary competition in selling the ICL to patients seeking surgery to correct refractive conditions lies not in similar products to the ICL, but in the much better known and widely available laser surgical procedures. Novartis (formerly Alcon), Abbott Medical Optics, previously known as Advanced Medical Optics or AMO (“Abbott”), and Bausch & Lomb (“B&L”) all market excimer lasers for corneal refractive surgery and promote their sales worldwide.

Phakic implants that compete with the ICL are also available in the marketplace. The three principal types of phakic IOLs (PIOLs) are (1) posterior chamber designs like the ICL, (2) iris clip anterior chamber PIOLs like the Artisan® and Artiflex® lenses made by Ophtec (Artisan® is distributed in the U.S. by AMO under the Verisyse® brand), and (3) angle-supported anterior chamber PIOLs like the Cachet™ made by Alcon and sold outside the U.S. We believe the ICL has compelling clinical advantages over the other lenses, which are reflected in our estimated 75% market share of the global phakic IOL market. The ICL is the only foldable, minimally invasive PIOL approved for sale in the U.S.

As with the refractive market, the global cataract market is highly concentrated, with the top three competitors (Novartis, Abbott and B&L) combined accounting for approximately 71.0% of total market revenue, according to a 2012 report by Market Scope, LLC, a publisher of ophthalmic industry analysis.

Regulatory Matters

Nearly all countries where we sell our products have regulations requiring advance approval or certification of medical devices. Various federal, state, local and foreign laws also apply to our operations, including, among other things, working conditions, laboratory, clinical, 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 and the Middle East have minimal regulatory requirements, while many others, such as Japan, have requirements of similarly stringency to those of the FDA. 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 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 July 2011 the Institute of Medicine published a study requested by the FDA on whether legislative, regulatory or administrative changes are needed to the FDA's 510(k) process. The Institute found "that the current 510(k) process is flawed based on its legislative foundation. Rather than continuing to modify the 35-year-old 510(k) process . . . the FDA's finite resources would be better invested in developing an integrated premarket and post market regulatory framework that provides a reasonable assurance of safety and effectiveness throughout the device life cycle." The Institute recommended additional data gathering to develop such a new framework. 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 any of 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 demonstrate independently 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 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. The FDA holds panels 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. The FDA makes this decision 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 manufacturer may implement a change that *enhances* safety 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.

Our IOLs, ICLs, and AquaFlow Devices are Class III devices, and our lens injector systems 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 injector systems.

Oversight of compliance with quality, medical device reporting and other regulations. Both before and after we release a product commercially, 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 and requirements, such as restrictions on advertising and promotion. The Good Manufacturing Practice (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 the devices, detain or seize adulterated or misbranded medical devices, or ban the 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. The FDA's BIMO Division, reviews our activities as a sponsor of clinical research. 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.

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, of the Monrovia, California facility on January 25, 2012, and of the Aliso Viejo, California facility on November 22, 2010. The 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

inspections of the Monrovia, California and Aliso Viejo, California facilities 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.

Status of TICL Submission. STAAR submitted a Pre-Market Approval Application (PMA) supplement for the TICL to the FDA on April 28, 2006, which the agency has designated as a panel-track supplement. In August 2007, following negative inspectional observations and a Warning Letter from FDA's BIMO, the FDA Office of Device Evaluation placed an integrity hold on STAAR's TICL application. Over a two-year period STAAR took a number of corrective actions to address BIMO's concerns and to remove the integrity hold, including engaging an independent third party to conduct a 100% 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. On July 21, 2009, the FDA notified STAAR that as a result of STAAR's corrective actions the FDA had removed the integrity hold on our application for approval of the TICL, and would resume its consideration of the application. During August and September 2009, the agency and STAAR resolved a number of questions related to the TICL supplement in an interactive process. On February 3, 2010, STAAR received a letter of deficiency from the FDA outlining additional questions. On August 2, 2010, we responded to the FDA's deficiency letter. After that response, STAAR was in dialogue with the agency, working interactively to resolve a series of follow-up questions. On April 22, 2011, STAAR responded to the questions from the agency, which concerned the basis for an increase in the number of reported patient follow-up visits following the independent third party audit of the clinical data, and has responded to additional follow-up questions after that date. On November 29, 2011, STAAR received a letter of deficiency from FDA further questioning the clinical data, specifically the inclusion of patient data that was obtained outside the study windows, requesting additional information on the lens design and a validation report for the Toric ICL power calculation software. After further interactions with the FDA throughout 2012, on November 15, 2012, STAAR submitted (1) clinical data showing no statistical difference in the clinical outcomes with or without the patient data that was obtained outside the study windows, (2) engineering data regarding the lens design, and (3) a validation report for the Toric ICL power calculation software. STAAR cannot predict when, or if, the FDA may grant approval of the Toric ICL.

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 *Conformité Européenne* 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 ICL and TICL products, IOLs, injector systems 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 are 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 largely 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 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 ICL and Toric 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 focus on furthering technological advancements in the ophthalmic products industry through the development of innovative premium ophthalmic products (lenses and delivery systems there for), materials and designs. We maintain an active internal research and development programs, which also includes clinical activities and regulatory affairs and is comprised of 30 employees. In order to achieve our business objectives, we will continue our investment in research and development.

During the last few years STAAR has regularly introduced new products from its pipeline of research and development projects. For example, during 2011, STAAR introduced the ICL V4c with CentraFLOW™ technology in Europe and other territories that recognize the CE Mark, and launched the Toric ICL in Japan. During 2010 it introduced the nanoPOINT™ 2.0 microincision injector for the ICL and launched an expanded range of ICL products in countries that accept the CE Mark. 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 Affinity Collamer IOL. Outside the U.S., in 2009 STAAR introduced the KS-X Preloaded Hydrophobic Acrylic Injector System in Europe and the KS-Ni Preloaded Silicone IOL Injector System in Japan. In 2012, STAAR introduced the KS-SP Preloaded Hydrophobic Acrylic Injector System in Japan and limited markets in Europe. The KS-SP differs from the KS-X by containing a single piece rather than three piece hydrophobic lens. During the first half of 2013 STAAR will introduce the nanoFLEX™ Toric Collamer IOL in countries that accept the CE Mark.

During 2013, our goal is to continue our focus on research and development in the following areas:

- Enhancements to the ICL that may simplify the procedure and further improve its efficacy;
- Development of preloaded injector systems for Collamer ICLs and IOLs;
- Development of a global hydrophobic acrylic IOL platform;
- Development of presbyopia-correcting IOLs and ICLs; and
- Approval of a silicone preloaded injector system for the U.S.

Research and development expenses were approximately $6.4 million, $5.9 million, and $5.7 million for our 2012, 2011, and 2010 fiscal years, respectively. STAAR expects to invest approximately 9-10% of sales for research and development in 2013.

Environmental Matters

We are 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 affect materially our capital expenditures, earnings or competitive position. We 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 1, 2013, STAAR's principal subsidiaries were STAAR Surgical AG in Switzerland and STAAR Japan Inc., both of which STAAR wholly owns. The activities of each are described above.

Employees

As of March 1, 2013, we employed approximately 301 persons.

Code of Ethics

STAAR has adopted a revised Code of Business Conduct and Ethics that applies to all of its directors, officers, and employees. The Code of Business Conduct and Ethics is posted on our website, www.staar.com — *Investor Information: 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, Current Reports on Form 8-K and amendments to any 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 STAAR 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.

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.

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

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.

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.

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.

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.

intraocular – within the eye.

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.

iridotomy – a small hole created in the iris, usually made with a YAG laser. Prior to implantation of some ICL models a YAG *peripheral* iridotomy is made in an obtrusive area at the periphery of the iris to ensure continued fluid flow in the eye after implantation. The ICL V4c model has a central port for fluid flow, which eliminates the need for an iridotomy or iridectomy.

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.

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.

ophthalmologist – a surgeon who specializes in the diseases and disorders of the eye and the visual pathway related to it.

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.

Preloaded Injector - a silicone or acrylic IOL packaged and shipped in a pre-sterilized, disposable injector. This differs from the conventional method of packaging IOLs, which 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.

QSR - The FDA's Quality System Regulation, or current Good Manufacturing Practice (cGMP) includes requirements related to the methods used in, and the facilities and controls used for, designing, manufacturing, packaging, labeling, storing, installing, and servicing of medical devices intended for human use. The regulation sets forth the framework for medical device manufacturers to follow in achieving quality requirements.

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 ICL 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.

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.

three-piece IOL – a three-piece IOL has a central, disk-shaped optic and two spring-like 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.

YAG – an acronym for yttrium-aluminum-garnet, a mineral crystal. Lasers using neodymium-doped yttrium aluminium garnet crystals (Nd:YAG) generate a high-energy beam that can be used in a number of ophthalmic procedures, including creating iridotomies before implantation of some models of the ICL.

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 below the known, significant risk factors that could affect our business and affect the expectations reflected in our forward-looking statements.

Risks Related to Our Business

We compete with much larger companies.

Our competitors, including Novartis (formerly Alcon), Abbott (formerly Advanced Medical Optics, or AMO) and Bausch & Lomb have much greater financial resources than we do and some of them have large international markets for a full suite of ophthalmic products. Their greater resources for research, development and marketing, and their greater capacity to offer comprehensive products and equipment to providers, make it difficult for us to compete. In the past, we have lost significant market share in IOL sales to some of our competitors.

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 advertising and promotional activities as well as 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 on January 25, 2012, STAAR believes that it is substantially in compliance with the FDA's Quality System Regulations and Medical Device Reporting regulations. However, past q uality system deficiencies observed at STAAR have led to FDA Warning Letters and delays in product approvals until we resolved agency concerns. Past deficiencies in clinical study procedures, practices and documentation related to the TICL led the FDA to place an integrity hold on the TICL application in August 2007, which was lifted in July 2009.

STAAR's ability to continue its U.S. business depends on the continuous improvement of its quality systems and constant vigilance in 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 Visian Toric ICL, which could have a significant U.S. market, has been considerably delayed.

An important part of STAAR's ICL product portfolio is the Toric ICL, or TICL, a variant of the ICL that corrects both astigmatism and myopia in a single lens and that has been marketed outside the U.S. since 2001. STAAR believes the TICL has a significant potential market in the U.S. and could accelerate growth of the overall refractive product line. STAAR submitted a supplemental PMA for the TICL in April 2006, which remains subject to FDA review and a number of pending questions under discussion with the agency. Without the Toric ICL the ICL product line is not likely to reach its full market potential in the U.S., and STAAR cannot predict when or if the FDA will approve it.

The global nature of our business may result in fluctuations and declines in our sales and profits.

Our products are sold in approximately 60 countries. Sales from international operations make up a significant portion of our total sales. For the fiscal year ended December 28, 2012, sales from international operations were 81% 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 sales and expenses are incurred in a different currency from the local currency. Our most significant currency exposures are to the Japanese yen, the 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. face a number of risks and potential costs, enjoy less stringent protection of intellectual property and face economic, political and social uncertainty in some countries, especially in emerging markets. Our continued success as a global company depends, in part, on our ability to develop and implement policies and strategies that are effective in anticipating and managing these and other risks in the countries where we do business. These and other risks may have a material adverse effect on our operations in any particular country and on our business as a whole. We price some of our products in U.S. dollars, and as a result changes in exchange rates can make our products more expensive in some offshore markets and reduce our sales. Inflation in emerging markets also makes our products more expensive there and increases the credit risks to which we are exposed.

We 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 detrimental 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. We do not maintain insurance policies to cover the cost of replacing the services of any of our key employees who may unexpectedly die or become disabled.

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

During 2011 STAAR achieved net income from continuing operations after reporting losses for more than ten years. During 2012 STAAR reported a loss from continuing operations on a GAAP basis. STAAR's future profitability is challenged by the competitive nature of our industry and the other risks to our business detailed herein. We have an accumulated deficit of $132.5 million as of December 28, 2012.

We rely and depend on independent distributors in international markets.

Except for the U.S., Canada, Japan, and Spain, STAAR sells its products through independent distributors who generally control the importation and marketing of our product within their territories. We generally grant exclusive rights to these distributors and rely on them to understand local market conditions, to diligently sell our products and to comply with local laws and regulations. Our agreements with distributors and local laws can make it difficult for us to quickly change from a distributor who we feel is underperforming. If we do terminate an independent distributor, we may lose customers who have been dealing with that distributor. Because we do not have local staff in most of the areas covered by independent distributors, it may be difficult for us to detect failures in our distributors' performance or compliance. Actions by independent distributors that are beyond our control could result in flat or declining sales in that territory, harm to the reputation of our company or its products, or legal liability. For example, in 2012, sales to our independent distributor in Korea, our largest market, declined by 18%.

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 (FCPA). The risk that unauthorized conduct may go undetected will always be greater in foreign subsidiaries.

Non-compliance with anti-corruption laws could lead to penalties or harm our reputation.

We are subject to anti-corruption laws in the jurisdictions in which we operate, including the FCPA. Any failure to comply with these laws, even if inadvertent, could result in significant penalties or otherwise harm our reputation and

business. Our reliance on foreign subsidiaries and independent distributors demands a high degree of vigilance in maintaining our policy against participation in corrupt activity. In many of our markets outside the U.S., doctors and hospital administrators may be deemed government officials. Other U.S. companies in the medical device and pharmaceutical field have faced criminal penalties under the FCPA for allowing their agents to deviate from appropriate practices in doing business with such individuals.

Unfavorable economic conditions hurt sales of our refractive products.

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. Laser refractive surgery experienced a significant decrease in demand globally with the recession that began in mid-2008, and has not fully recovered. While ICL sales have continued to grow globally, STAAR believes that negative economic conditions have slowed growth, especially in the U.S. Economic stagnation, lack of consumer confidence or new recessions in any of our key markets, including but not limited to Korea, China or Spain, could further slow ICL sales growth or, if severe, cause declines in sales. Because the 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. 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. In May 2009 the FDA issued a cautionary letter to surgeons regarding promotion and advertising of lasers used in refractive surgery. In October 2009 the FDA, in collaboration with the National Eye Institute and the U.S. Department of Defense, began a major study on the quality of life for patients after LASIK surgery, which is ongoing. The results of this study could amplify concerns about complications of laser refractive surgery. While these concerns could encourage patients and doctors to select the ICL as an alternative, they could also decrease patient interest in all refractive surgery, including ICL. Outside the U.S., in February 2012, it was widely reported throughout the Asia Pacific region that Dr. Ray Tsai, a prominent ophthalmologist in Taiwan questioned the safety of LASIK surgery, and would no longer perform the procedure. We believe this negative publicity decreased patient interest in the Asia Pacific region in LASIK as well as all other refractive procedures. Depending on the nature and severity of future negative publicity about refractive surgery, the growth of ICL sales 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.

We may not realize the expected benefits of our manufacturing consolidation project and tax strategies.

Beginning in 2011 STAAR has invested significant resources in a manufacturing consolidation project and a tax strategy initiative, and it expects to invest several million dollars to complete the projects. The goal of these projects is to increase profit margins by improving manufacturing efficiency, simplifying administrative and regulatory functions, and reducing tax liabilities. We cannot assure that we will achieve the expected benefits of these initiatives. Among other things, costs could exceed current estimates, product manufacturing transfers can be affected by delays or cause supply interruptions, changes in tax laws could reduce or eliminate expected benefits of some of our tax strategies, and future profit margins can be affected by a variety of factors unrelated to our level of manufacturing efficiency.

Our manufacturing consolidation plan exposes us to risk.

Transferring the manufacturing of medical devices is more expensive, time-consuming and risky than similar transfers in less regulated industries. In our major markets, regulatory approval to sell our products is generally limited to the current manufacturing site, and changing the site will require applications to and approval from regulatory bodies prior to commercialization. To satisfy our own quality standards as well as regulations, we must follow strict protocols to confirm that products made at a new site are equivalent to those made at the currently approved site. Even minor changes in equipment, supplies or processes require validation. While STAAR has placed a priority on maintaining the continuity and quality of its product supply, including increasing its inventory as safety stock during the consolidation, unanticipated delays or difficulties in the transfer process could interrupt our supply of products. Any sustained interruption in supply could cause us to lose market share and harm our business. In addition, after we complete our consolidation plan, we will no longer have an alternative source of supply for the products we manufacture (for example, Collamer and silicone IOLs, Collamer ICLs and delivery systems) in the event of an earthquake or other event that disrupts our manufacturing activities in California.

Disruptions in our supply chain or failure to adequately forecast product demand could result in significant delays or lost sales.

The loss of a material supplier could significantly disrupt our business. In some cases, we obtain components used in certain of our products from single sources. If we experience difficulties acquiring sufficient quantities of required materials or products from our existing suppliers, or if our suppliers are found to be non-compliant with the FDA's QSRs, cGMPs or other applicable laws, obtaining the required regulatory approvals to use alternative suppliers may be a lengthy and uncertain process during which we could lose sales.

Any failure by us to forecast demand for, or to maintain an adequate supply of, the raw material and finished product could result in an interruption in the supply of certain products and a decline in sales of that product. The manufacturing process to create the raw material necessary to produce some of our products is technically complex and requires significant lead-time. If our suppliers are unable to meet our manufacturing requirements, we may not be able to produce a sufficient amount of materials or products in a timely manner, which could cause a decline in our sales. For example, our supply of acrylic lenses from a third party supplier is limited by manufacturing capacity constraints, which will result in backlog in demand.

Also, our sources of supply for raw materials can be threatened by shortages 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 the substitute supplier's regulatory compliance and the quality standards of the replacement material could significantly delay production and materially reduce our sales. We mitigate this risk by maintaining adequate inventory of raw materials when practical and identifying secondary suppliers, but we cannot entirely eliminate the risk. 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, we obtain the proprietary collagen-based raw material used to manufacture our IOLs, ICLs and the AquaFlow Device internally from a sole source, 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 STAAR. The loss of our external supply source for silicone could also cause us material harm.

We may experience backlog in ICL orders due to rapid increases in demand.

The challenge of maintaining inventory across the large number of ICL models, combined with an unexpectedly large increase in demand for the ICL, may result in a backlog in customer orders that are financially significant. In addition, delays in filling orders can result in lost sales if alternative refractive treatments are available to the patient. If we are unable to ramp up production to meet increased demand we may not achieve our growth targets.

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 that exceeds our insurance coverage could materially harm our business, financial condition and results of operations. Even if a product liability loss is covered by an insurance policy, we must generally pay for losses until they reach the level of the policy's stated deductible or retention amount after which the insurer begins paying. 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 may have limited ability to fully use our recorded tax loss carryforwards.

We have accumulated approximately $122.5 million of U.S. federal tax net operating loss carryforwards as of December 28, 2012, which can be used to offset taxable income in future quarters if our U.S. operations become profitable. If unused, these tax loss carryforwards will begin to expire between 2020 and 2032. Currently, when we generate profits on a consolidated basis, those profits are generated outside the U.S. and are subject to income taxes that we cannot offset with U.S. loss carryforwards. As part of our global consolidation strategy we expect to increase our profits enabling us to begin utilizing our tax loss carryforwards in the U.S., but unexpected changes in tax laws or delays and complications in our consolidation efforts could prevent us from realizing the benefits of this tax strategy. Moreover, under the current tax laws, 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 our U.S. operations generate significant profits.

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.

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. 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 or renewing existing debt facilities. An inability to secure additional financing if it is needed in the future could require us to forego opportunities for expansion, reduce existing operations, or even jeopardize our ability to continue operations.

The terms of our debt facilities impose restrictions on our business.

Our current or future indebtedness may limit our flexibility in planning for, or reacting to, changes in our business and the industry in which we operate and, consequently, may place us at a competitive disadvantage to our competitors. The operating and financial restrictions and covenants in our debt facilities may adversely affect our ability to finance future operations or capital needs or to engage in new business activities.

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 could suffer 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. We plan to consolidate all of our manufacturing to our Monrovia, California facility, which will increase our exposure to a disaster that occurs in that area. Our insurance for property damage and business interruption may not be sufficient to cover any particular loss. We do not carry insurance or reserve funds for interruptions or potential losses arising from earthquakes or terrorism.

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. During 2012, we contributed $234,000 to our Swiss Plan, and although we did not contribute to our Japan Plan, we made a benefit payment of $65,000.

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 has maintained and administered the Japan Plan, including paying the pension benefits as they are due solely from its continuing operations. STAAR Japan is not required to make any contributions to the Japan Plan in order to meet future pension benefit obligations, and does not expect to do so. As a result, 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 $3.0 million ($1.2 million for the Japan Plan and $1.8 million for the Swiss Plan) as of December 28, 2012.

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.

Our activities involve hazardous materials and emissions and may subject us to environmental liability.

Our manufacturing, research and development activities involve the use of hazardous materials. Federal, state and local laws and regulations govern the use, manufacturing, storage, handling and disposal of these materials and certain waste products in the places where we have operations. 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.

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. For example, we produce the collamer material used in our ICL products and many of our IOL products. If we were unable to continue collamer production, we are unaware of an alternative supplier. While our insurance covers lost revenue resulting from business interruption for a number of causes, if we have no product supplies for an extended period we could suffer an unrecoverable loss of market share. We do not have insurance coverage for revenue lost in a business interruption following an earthquake. Once completed, our manufacturing consolidation plan could increase the risk of harm to our business from a natural disaster in California.

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 depend on information technology networks and systems, including the Internet, to process, transmit and store electronic information. In particular, our information technology infrastructure handles 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. Also, certain of our information technology systems are not redundant, and our disaster recovery planning is not sufficient for every eventuality. Despite any precautions we may take, such problems could result in, among other consequences, interruptions in our

services, which could harm our reputation and financial 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 significantly change our reported results of operations or financial condition.

Our publicly filed SEC reports may be reviewed by the SEC.

The reports of publicly traded companies are subject to review by the SEC from time to time for the purpose of assisting companies in complying with applicable disclosure requirements and to enhance the overall effectiveness of companies' public filings, and comprehensive reviews of such reports are now required at least every three years under the Sarbanes-Oxley Act of 2002. The SEC reviews may be initiated at any time. While we believe that our previously filed SEC reports comply, and we intend that all future reports will comply in all material respects with the published rules and regulations of the SEC, we could be required to modify or reformulate information contained in prior filings as a result of an SEC review. Any modification or reformulation of information contained in such reports could be significant and could result in material liability to us and have a material adverse impact on the trading price of our common stock.

Acquisitions of technologies, products, and businesses could disrupt our business, involve increased expenses and present risks not contemplated at the time of the transactions.

We may consider and, as appropriate, make acquisitions of technologies, products and businesses that we believe are complementary to our business. Acquisitions typically entail many risks and could result in difficulties in integrating the operations, personnel, technologies and products acquired, some of which may result in significant charges to earnings. Issues that must be addressed in acquiring and integrating the acquired technologies, products and businesses into our own include:

- conforming standards, controls, procedures and policies, operating divisions, business cultures and compensation structures;
- retaining key employees;
- retaining existing customers and attracting new customers;

· consolidating operational infrastructure, including information technology, accounting systems and administration;

· mitigating the risk of unknown liabilities; and

· managing tax costs or inefficiencies associated with integrating operations.

If we are unable to successfully integrate our acquisitions with our existing business, we may not obtain the advantages that the acquisitions were intended to create, which may materially adversely affect our business, and our ability to develop and introduce new products. Actual costs and sales synergies, if achieved at all, may be lower than we expect and may take longer to achieve than we anticipate. Furthermore, the products of companies we acquire may overlap with our products or those of our customers, creating conflicts with existing relationships or with other commitments that are detrimental to the integrated businesses.

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 demonstrating to a sufficient number of eye-care professionals the overall benefits of using them.

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

We spent about 10.1% of our sales on research and development during the fiscal year ended December 28, 2012, and we expect to spend similar amounts 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 and the new Medical Device Tax could reduce sales of our products or make them less profitable.

Certain of our products, such as our IOLs, are used in procedures that are typically covered by health insurance, HMO plans, Medicare, Medicaid, or other governmental sponsored programs both in and outside the U.S. 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. 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 Patient Protection and Affordable Care Act will significantly change the system of public and private health care reimbursement, and future legislation will likely consider further changes that may impact availability and/or pricing for cataract surgery where our IOLs are used. 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. In addition, the Patient Protection and Affordable Care Act includes a 2.3% excise tax on medical devices sold in the U.S., which applies to sales of our IOLs and ICLs. This could reduce the sales of our products or make them less profitable.

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 FDA, 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 and other regulatory bodies for approval. Obtaining approval can be a long and expensive process, and approval is never certain. For example, the FDA or another country's regulatory agency, could require us to conduct an additional clinical trial prior to approval of a product and such clinical trial could take a long time and have substantial expense. 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.

Laws pertaining to healthcare fraud and abuse could materially adversely affect our business, financial condition and results of operations.

We are subject to various federal, state and foreign laws pertaining to healthcare fraud and abuse, including anti-kickback laws, physician self-referral laws and false claims laws. Violations of these laws are punishable by criminal and civil sanctions, including, in some instances, exclusion from participation in federal and state healthcare programs, including Medicare, Medicaid, Veterans Administration health programs and TRICARE. Similarly, if the physicians or other providers or entities with whom we do business are found to be non-compliant with applicable laws, they may be subject to sanctions, which could indirectly have a negative impact on our business, financial condition and results of operations. While we believe that our operations are in material compliance with such laws, because of the complex and far-reaching nature of these laws, there can be no assurance that we would not be required to alter one or more of our practices to be in compliance with these laws. Indeed, recent changes in state laws and model codes of ethics have already required us to alter certain of our compliance efforts. For example, in April 2009, Massachusetts issued regulations governing the conduct of pharmaceutical and medical device manufacturers with respect to healthcare practitioners. This regulation became effective on July 1, 2009 and sets forth what medical device manufacturers may and may not permissibly do with respect to providing meals, sponsoring continuing medical education and otherwise providing payments or items of economic benefit to healthcare practitioners located within the state. Additionally, the regulation requires medical device manufacturers to have in place robust fraud and abuse compliance programs. Other states (e.g., California, Vermont and Nevada) have adopted similar laws. These laws and regulations act to limit our marketing practices, require the dedication of resources to ensure compliance, and expose us to additional liabilities.

In addition, the recent Health Care Reform Law, among other things, amends the intent requirement of the federal Anti-Kickback Statute and certain criminal healthcare fraud statutes so that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. The Health Care Reform Law also provides that the government may assert that a claim including items or services resulting from a violation of these statutes constitutes a false or fraudulent claim for purposes of the civil False Claims Act or the civil monetary penalties statute.

Any violations of these laws or regulations could result in a material adverse effect on our business, financial condition and results of operations. In addition, changes in these laws, regulations, or administrative or judicial interpretations, may require us to further change our business practices or subject our existing business practices to legal challenges, which could have a material adverse effect on our business, financial condition and results of operations.

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 internal 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.

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. 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.

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. When our patents covering our products expire, our competitors may introduce products using the same technology. As a result of this possible increase in competition, we may need to reduce our prices to maintain sales of our products, which would make them less profitable. If we fail to develop and successfully launch new products prior to the expiration of patents for our existing products, our sales and profits with respect to those products could decline significantly. We may not be able to develop and successfully launch more advanced replacement products before these and other patents expire.

Risks Related to Ownership of Our Common Stock

Our charter documents could delay or prevent an acquisition or sale of our company.

Our Certificate of Incorporation empowers the Board of Directors to establish and issue a class of preferred stock, and to determine the rights, preferences and privileges of the preferred stock. These provisions give the Board of Directors the ability to deter, discourage or make more difficult a change in control of our company, even if such a change in control could be deemed in the interest of our stockholders or if such a change in control would provide our stockholders with a substantial premium for their shares over the then-prevailing market price for the common stock. Our bylaws contain other provisions that could have an anti-takeover effect, including the following:

- stockholders have limited ability to remove directors;

- stockholders cannot act by written consent;

- stockholders cannot call a special meeting of stockholders;

- the above limitations on stockholder action can be changed only by a 66-2/3% supermajority vote 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. Also, STAAR has filed a universal “shelf registration statement” with the Securities and Exchange Commission. The shelf registration statement covers the future public offering and sale of up to $75 million in equity or debt securities or any combination of such securities. While STAAR currently has no plans to issue any securities under the shelf registration, sales of common or preferred stock under the shelf registration or in other transactions 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. It ranged from $5.05 to $11.37 per share during the year ended December 28, 2012. 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. 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

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 may relate to contractual rights and obligations, employment matters, and claims of product liability. STAAR maintains insurance coverage for product liability claims but may not be insured against other potentially material claims. While the Company is not aware of any claims 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. Mine Safety Disclosures

None.

PART II

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

Market Information

Our common stock is traded on the Nasdaq Global Market (Nasdaq) under the symbol "STAA." The following table sets forth the high and low per share sale prices of our common stock as reported by Nasdaq.

Period	High	Low
Year ended December 28, 2012		
Fourth Quarter	$7.71	$5.05
Third Quarter	8.43	5.14
Second Quarter	11.21	7.38
First Quarter	11.37	9.65
Year ended December 30, 2011		
Fourth Quarter	$11.50	$7.20
Third Quarter	8.50	4.48
Second Quarter	5.92	4.56
First Quarter	6.41	5.05

Holders

As of March 1, 2013, there were approximately 456 record holders of our Common Stock.

Dividends

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.

Stock Performance Graph

This performance graph shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the Exchange Act), or incorporated by reference into any filing of STAAR Surgical Company under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

The following graph shows a comparison from December 28, 2007 through December 28, 2012 of the total performance of the following:

- STAAR Surgical Company;
- The Nasdaq Stock Market;
- a peer group we have selected consisting of 12 companies within our industry or closely related industries: Anika Therapeutics (ANIK); Cutera Inc. (CUTR); Cynosure Inc. (CYNO); Integra LifeSciences Holdings Corp. (IART); Iridex Corp. (IRIX); LCA Vision Inc. (LCAV); Merit Medical Systems, Inc. (MMSI); Palomar Medical Technologies Inc. (PMTI); Solta Medical Inc. (SLTM); Synergetics USA Inc. (SURG); Syneron Medical Ltd. (ELOS); and Volcano Corporation (VOLC).

Returns in the graph below reflect historical results; we do not intend to suggest they predict future performance. The data assumes $100 was invested on December 28, 2007 in STAAR common stock and in each of the composite indices, and that dividends (if any) were reinvested. We have never paid dividends on our common stock and have no present plans to do so.

Total Returns Index for Fiscal Years:	2007	2008	2009	2010	2011	2012
STAAR Surgical Company	100.00	92.69	119.23	234.62	403.46	223.85
The Nasdaq Stock Market (US and Foreign Companies)	100.00	61.55	86.42	102.02	101.15	116.51
Peer Group	100.00	74.16	82.89	103.83	89.73	93.18

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 28, 2007.

Item 6. Selected Financial Data

The following table sets forth selected consolidated financial data with respect to the five most recent fiscal years ended December 28, 2012, December 30, 2011, December 31, 2010, January 1, 2010, and January 2, 2009. The selected consolidated statement of operations data set forth below for each of the three most recent fiscal years, and the selected consolidated balance sheet data set forth below at December 28, 2012 and December 30, 2011, are derived from our consolidated financial statements, which have been audited by BDO USA, LLP, our independent registered public accounting firm, as indicated in their report included in this Annual Report. The selected consolidated statement of operations data set forth below for each of the two fiscal years in the periods ended January 1, 2010 and January 2, 2009 and the consolidated balance sheet data set forth below at December 31, 2010, January 1, 2010, and January 2, 2009, are derived from audited consolidated financial statements of the Company not included in this Annual Report. We have adjusted all prior periods presented to account for Domilens Gmbh divestiture on March 2, 2010 and present Domilens as a discontinued operation. The selected consolidated financial data should be read in conjunction with the consolidated financial statements of the Company, and the Notes thereto, included in this Annual Report, and "Management's Discussion and Analysis of Financial Condition and Results of Operations" in Item 7.

	Fiscal Year Ended				
	December 28, 2012	December 30, 2011	December 31, 2010	January 1, 2010	January 2, 2009
	(In thousands except per share data)				
Statement of Operations					
Net sales	$63,783	$ 62,765	$ 54,958	$ 51,060	$ 49,770
Cost of sales	19,492	20,396	19,882	19,737	20,688
Gross profit	44,291	42,369	35,076	31,323	29,082
General and administrative	15,150	14,932	14,778	15,009	15,730
Marketing and selling	21,281	17,726	17,176	15,300	18,472
Research and development	6,444	5,868	5,724	5,893	7,938
Other general and administrative expenses	2,636	1,060	—	—	9,773
Operating income (loss)	(1,220)	2,783	(2,602)	(4,879)	(22,831)
Total other income (expense), net	701	(79)	(1,079)	(869)	(1,044)
Income (loss) before income taxes	(519)	2,704	(3,681)	(5,748)	(23,875)
Income tax provision	1,244	1,356	432	1,154	975
Income (loss) from continuing operations	(1,763)	1,348	(4,113)	(6,902)	(24,850)
Income from discontinued operations, net of income taxes	—	—	4,166	702	1,655
Net income (loss)	$(1,763)	$ 1,348	$ 53	$ (6,200)	$ (23,195)
Income (loss) per share from continuing operations – basic	$(0.05)	$ 0.04	$ (0.12)	$ (0.21)	$ (0.84)
	$(0.05)	$ 0.04	$ (0.12)	$ (0.21)	$ (0.84)

Income (loss) per share from continuing operations – diluted					
Income per share from discontinued operations, basic and diluted	$—	$ —	$ 0.12	$ 0.02	$ 0.05
Net income (loss) per share – basic	$(0.05)	$ 0.04	$ (.00)	$ (0.19)	$ (0.79)
Net income (loss) per share – diluted	$(0.05)	$ 0.04	$ (.00)	$ (0.19)	$ (0.79)
Weighted average shares outstanding-basic	36,253	35,434	34,825	32,498	29,474
Weighted average shares outstanding –diluted	36,253	36,878	34,825	32,498	29,474
Balance Sheet Data					
Working capital	$26,125	$ 24,638	$ 16,539	$ 13,466	$ 10,807
Total assets	54,759	49,006	40,585	58,681	52,582
Long-term notes payable, net of discount	—	—	—	* —	4,414
Other long-term liabilities	5,068	5,532	4,711	3,887	3,910
Stockholders' equity	31,742	29,458	22,427	21,070	16,027

* included in current liabilities

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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," "p "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

STAAR's strategy is to be valued as a leading global provider of innovative intraocular lens system technologies. STAAR employs a commercialization strategy that focuses on achieving sustainable profitable growth.

Performance Against 2012 Key Operational Metrics

Two principal strategic goals guided STAAR's key operational metrics in 2012: to lay the groundwork for further growth and to achieve and maintain profitability. In pursuit of these goals, STAAR aligned its business initiatives

during 2012 along five key operational metrics that it used to gauge its performance during the year. Based on performance relative to our targets, on August 1, 2012, STAAR decreased the targets for three of the five metrics, and in final form they are as follows:

- Increase total revenue by high single digits for the full year.
- As discussed below in "*Results of Operations*," our total revenue increased by 2% in 2012.
- Grow ICL sales by 25% for the second half of 2012 and 20% for the full year.
- As discussed below in "*Results of Operations*," ICL sales grew 6% for the second half of 2012 and 9% for the year.
- Increase gross profit margins to achieve a level of 71% for the full year.
- As discussed below in "*Results of Operations*," gross profit margins increased from 67.5% in 2011 to 69.4% in 2012.
- Achieve profitability in three quarters of 2012.
- As discussed below in "*Results of Operations*," we achieved profitability on a GAAP basis only in the first quarter of 2012.
- Manage the manufacturing consolidation with no material disruption to customer supply requirements.
- Our consolidation efforts proceeded according to our plans and we expect this to continue during 2013. As a result of certain consolidation-related expenses being pulled forward from 2013, spending levels were higher than projected for the year ended December 28, 2012.

Other Highlights

General

In 2012, STAAR increased its investment in the future by increasing research and development expense by 10% over prior year to 10% of net sales. We expect this investment to result in revenue-enhancing, patent-protected next-generation products. STAAR also increased its investment in its sales and marketing teams by hiring 17 new sales and marketing employees domestically and throughout our top eleven global refractive markets. The new marketing employees are focusing on enhancing global consumer awareness initiatives for the ICL product line, expanding social media messaging, including a redesigned web site, increasing support for ICL awareness campaigns and added consumer marketing in the Asia Pacific region. These new hires, along with their increased marketing activities, resulted in a 20% increase in sales and marketing expense. In addition, during 2012 STAAR transitioned its sales efforts in Spain from a distributor to direct sales model and incurred approximately $1.2 million in transition expenses related to this change. STAAR also increased its manufacturing consolidation efforts in 2012 in preparation of transferring Swiss and Japanese manufacturing activities to our Monrovia facility. These non-recurring consolidation and facility expansion efforts increased our expenses by $1.6 million over consolidation efforts in 2011.

Global Visian ICL and TICL Sales

STAAR is the only company with approval to sell a posterior segment phakic IOL, known as the ICL. In 2012, sales of the ICL products represented approximately 55% of STAAR’s business. STAAR continues to focus its ICL marketing and sales efforts in the top eleven refractive markets, based on the success of this strategy from 2010 through 2012. These markets include the U.S., Japan, Korea, China, India, Spain, Middle East, Germany, Italy, U.K., and Latin America.

In September 2011, STAAR launched the V4c model of the ICL with CentraFLOW technology, the KS-AquaPort™ in countries that recognize the CE Mark. The CentraFLOW technology uses a proprietary port in the center of the ICL optic of a size intended to optimize the flow of fluid within the eye, and eliminates the need for the surgeon to perform a YAG peripheral iridotomy procedure days before the ICL implant or a surgical iridotomy at time of implant. By simplifying the procedure and increasing patient comfort, the ICL with CentraFLOW technology makes the superior visual outcomes of the ICL available through a surgical implantation experience closer to LASIK, which should attract new surgeons and patients to the product.

The launch of ICLV4c follows the September 2010 introduction of the ICLV4b model, which offers an expanded range of correction, in territories that recognize the CE Mark. The expanded range includes ICLs with lower levels of myopia correction in quarter-diopter increments, Toric hyperopic ICLs to treat astigmatism and far-sightedness, and

Toric ICLs in the low to zero range of myopia to treat patients primarily affected by astigmatism. These product line extensions more than double the number of patients who could benefit from products in Europe and other territories that accept the CE Mark.

STAAR believes that increased regulatory approval of the ICL with CentraFLOW technology beyond countries that recognize the CE Mark, such as Korea, India and Latin America, will improved the competitiveness of the ICL product line and help move STAAR closer to its goal of positioning the ICL and TICL throughout the world as primary choices for refractive surgery. ICL products now address, in countries where approved, all degrees of refractive error that can be treated with laser eye surgery, as well as moderate and severe errors beyond the effective range of laser eye surgery.

In some key markets of the Asia Pacific region, as well as the U.S., STAAR has not yet introduced the ICLV4b model. In those countries, STAAR is seeking approval of the ICL with CentraFLOW technology and plans to move directly to that model as quickly as regulatory timelines allow.

STAAR’s ability to maintain or accelerate the rate of growth in ICL sales will partly depend on continued improvement in worldwide economic conditions and progress with regulatory agencies. ICL surgery is a relatively expensive elective procedure and is seldom reimbursed by insurers or government agencies. STAAR believes that the global recession reduced overall demand for refractive surgery particularly in the U.S., and it has been reported that consumer spending and consumer confidence has not returned to pre-recession levels.

We consider ICL sales growth in the U.S. market 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 ICL was approved by the FDA for treatment of myopia on December 22, 2005. STAAR submitted a Pre-Market Approval Application supplement for the Toric ICL to the FDA on April 28, 2006, and that application remains open and pending (*See, Item 1, "Regulatory Requirements in the United States, Status of TICL Submission."*). On October 9, 2012, STAAR submitted to the FDA a 180 day PMA Supplement regarding the ICL with CentraFLOW technology. After discussion with the FDA, we agreed to resubmit the Supplement as a pre-submission prior to submitting a revised PMA Supplement.

Spain has long been a large ICL market in Europe for STAAR. Because STAAR believes the potential of the Spanish market has not been fully realized, STAAR decided to shift from its independent distributor to a direct sales model when the distributor's contract expires in 2013. In the second quarter of 2012, STAAR had an opportunity to negotiate an early transition to the direct model, with the existing distributor to provide transitional services and ongoing logistics support for a fee. While the transition caused a short-term decline in revenues as the independent distributor ceased purchasing inventory and STAAR bought back the existing distributor inventory, STAAR believes that future revenues from Spain will increase through enhanced direct marketing efforts and by selling directly to customers. Additional transition expenses will be incurred during the transitional period until March 2013 and logistic expenses to our former distributor through the first quarter of 2015. The on-going weakness and uncertainty in the Spanish economy may affect the magnitude and timing of these future benefits.

Since 2011, STAAR experienced noteworthy growth in market penetration in China and Korea. However, in February 2012, it was widely reported throughout the Asia Pacific region that Dr. Ray Tsai, a prominent ophthalmologist in Taiwan questioned the safety of LASIK surgery, and would no longer perform the procedure. We believe this negative publicity decreased patient interest in China in LASIK as well as all other refractive surgeries. In addition, economic concerns in Korea as well as price competition among LASIK procedure centers adversely impacted our sales in Korea. Our distributor adjusted inventory levels. We expect sales to increase in China and Korea in 2013. While no assurance can be given regarding 2013 sales, through the first two months of 2013, our sales in Korea increased 60% over the first two months of 2012.

Global IOL Sales.

STAAR pioneered the development of folding lenses for use in cataract surgery, and IOLs represented approximately 41% of STAAR's business in 2012.

In September 2011, STAAR launched its nanoFLEX Collamer Single Piece IOL which can be injected through a 2.2 mm incision with the nanoPOINT™ Injector System, in the territories that recognize the CE Mark. STAAR received CE Mark approval to market its nanoFLEX toric IOL in November 2011, and expects to begin marketing the lens in 2013. nanoFLEX is STAAR's largest selling IOL product in U.S. markets and STAAR believes the lens can receive broad

commercial acceptance outside the U.S. STAAR hopes that the biocompatibility and outstanding optical properties of Collamer, with which surgeons have become acquainted through the ICL, will build interest in the nanoFLEX IOL worldwide. Availability of the toric version of the lens, which corrects pre-existing astigmatism at the time of cataract surgery, is expected to increase interest in the nanoFLEX technology outside the U.S.

In May, 2012, STAAR included in its Annual Report to the FDA notification of changes to the lens length and haptic design for the nanoFLEX IOL. On September 25, 2012, the FDA responded that we should submit these changes as a PMA Supplement. On November 19, 2012, STAAR amended its Annual Report to not include the modified nanoFLEX. The Company is assessing its options regarding the modified nanoFLEX IOL in the U.S., while it continues to sell the current version.

STAAR has marketed its silicone toric IOL since 1998 and believes that the addition of the nanoFLEX toric will make the product line more competitive with acrylic toric IOLs now in the market. Among other things, the nanoFLEX toric features an aspheric optic, and we believe the bio-adhesive nature of the Collamer material will provide excellent rotational stability, a key characteristic for toric lenses.

In the fourth quarter of 2012, STAAR launched in Japan and select markets in Europe a hydrophobic acrylic Preloaded IOL, featuring the popular single-piece IOL format, known as the KS-SP. The market favorably received the KS-SP and we received higher demand than originally forecasted. Due to manufacturing capacity constraints occurring at our third-party acrylic lens supplier, we currently are experiencing a backlog for the KS-SP, as well as the KS-X. The supplier cannot estimate whether or when their expanding manufacturing capabilities will be able to meet our increasing supply requirements. While we are exploring supply alternatives, there is no guaranty we will identify and validate an alternative supplier.

Among STAAR's initiatives to grow its IOL business are the following:

- we plan to introduce a preloaded injector for the nanoFLEX and nanoFLEX toric;

- we are seeking approval to introduce the silicone Preloaded IOL in the U.S. market to enhance our U.S. IOL offering and help STAAR maintain or increase its market share in the hospital-based segment;

- we plan to seek further approvals for the nanoFLEX and nanoFLEX Toric in an effort to build a global product franchise for Collamer IOLs; and

- we are researching presbyopia-correcting designs that leverage the unique optical properties of the Collamer material.

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.

Manufacturing Consolidation Project and Tax Strategy. During 2012 STAAR devoted significant resources to two initiatives: a project to consolidate global manufacturing, and development of a strategy to optimize our global organization for tax purposes. The goal of these strategies is to further improve upon gross profit margin by streamlining operations, thereby reducing costs and to increase profits in the U.S. to enable the Company to utilize its $122.5 million in net operating loss carryforwards, and at the same time, reduce income taxes in foreign jurisdictions where it pays tax.

STAAR currently manufactures its products in four facilities worldwide. It has developed a plan to methodically consolidate its manufacturing in a single site at its Monrovia, California location by the end of 2013, which is expected subsequently to yield significant savings in cost of goods and to lower our global administrative and regulatory costs.

By December 2012, all non-sterile IOLs were manufactured in the U.S., whereas they were previously manufactured in Japan. In December 2012, the Company began the first manufacturing ICLs in the U.S., whereas they were previously exclusively manufactured in Switzerland. While some U.S. manufactured IOLs were sold in December 2012, sales of U.S.-manufactured IOLs and ICLs will comprise a larger portion of our sales in 2013. This project, which is subject to significant risks, is further described under "*Risk Factors*, *"Our manufacturing consolidation plan exposes us to risk."*

STAAR expects its manufacturing consolidation initiatives to cost approximately $6 million over a three-year period, of which it spent approximately $2.6 million during 2012. Expenditures to date have largely consisted of severance, employee costs, professional fees to advisors and consultants and accruals for asset retirement obligations. Additionally, we expect to spend approximately $2.4 million in capital expenditures to consolidate our manufacturing.

In August 2012, STAAR entered into an eight year lease of an approximately 26,000 square foot building immediately adjacent to our current facility in Monrovia, California. The new building, which is accessible from the current facility via two hallways, will allow the Company to accommodate the needs associated with our previously announced manufacturing consolidation to Monrovia, as well as provide space for additional growth. The Company estimates the annualized cost of the new facility will increase Selling, General and Administrative expenses by approximately $625,000.

In addition, as STAAR's profitability grows, its liability for income taxes in various jurisdictions has also increased. STAAR has developed a strategy to minimize its future tax liabilities as its business grows. Among other things, STAAR seeks to utilize the approximately $122.5 million in net operating losses that it has accumulated in the U.S.

However, we cannot assure that we will achieve the expected benefits of these initiatives. Among other things, costs could exceed current estimates, product manufacturing transfers can result in delays or supply interruptions, changes in tax laws could reduce or eliminate expected benefits of some or our tax strategies, and future profit margins can be affected by a variety of factors unrelated to our level of manufacturing efficiency.

Backlog. The ICL is manufactured to precisely address refractive prescriptions across a broad range of correction, resulting in a large number of Stock Keeping Units (SKUs). The challenge of maintaining inventory in all models, can result in a backlog in customer orders. While the dollar amount of backlog orders is not currently significant in relation to our total annual sales, unexpectedly large orders for ICLs could increase our backlog. STAAR believes it has sufficient capacity to ramp up production levels to meet demand and that any backlogs will be temporary. However, delays in filling orders can result in lost sales if alternative refractive treatments are available to the patient. Because Toric ICLs treat an even greater variety of refractive errors and at times must be custom made for the patient, they are accustomed to a special order procedure and do not expect immediate delivery of Toric ICLs from inventory. In connection with our manufacturing consolidation project, we have built a safety stock of inventory of our primary products within the ICL and IOL product lines.

Our pre-loaded single piece acrylic IOL is currently experiencing backlogs due to high demand and manufacturing capacity constraints occurring at our third-party acrylic lens vendor. Although the supplier is working to resolve the issue, they cannot estimate whether or when their manufacturing capabilities will be able to meet our increasing supply needs. While we are exploring supply alternatives, there is no guaranty we will identify and validate an alternative supplier.

Status of U.S. TICL Submission.

As discussed above under the caption *"Business — Regulatory Matters,"* STAAR submitted a Pre-Market Approval Application (PMA) supplement for the TICL to the FDA on April 28, 2006, which the agency has designated as a panel-track supplement. On November 29, 2011, STAAR received a letter of deficiency from FDA further questioning the clinical data, specifically the inclusion of patient data that was obtained outside the study windows, requesting additional information on the lens design and a validation report for the Toric ICL power calculation software. After further interactions with the FDA throughout 2012, on November 15, 2012, STAAR submitted (1) clinical data showing no statistical difference in the clinical outcomes with or without the patient data that was obtained outside the study windows, (2) engineering data regarding the lens design, and (3) a validation report for the Toric ICL power calculation software. The U.S. represents the largest refractive procedure market and STAAR will continue to seek approval. STAAR cannot predict when, or if, the FDA may grant approval of the Toric ICL.

Financing Strategy

On December 28, 2012, in response to an offer made by the bank, STAAR Japan amended its existing line of credit agreement with Mizuho Bank. The amended agreement authorizes the Company to increase its borrowings from up to 300,000,000 Yen (approximately $3.5 million based on the exchange rate on December 28, 2012), at an interest rate equal to the Tokyo short-term prime interest rate (approximately 1.475% as of December 28, 2012) plus 1.125%, for a total effective rate of 2.6%, to a new limit of 500,000,000 Yen (approximately $5.9 million based on the exchange rate on December 28, 2012), at a lower interest rate equal to the Tokyo short-term prime interest rate (approximately 1.475% as of December 28, 2012). The credit facility may be renewed for an agreed upon term (the current line expires on March 28, 2013). The credit facility is not collateralized. The Company had 200,000,000 Yen outstanding on the line of credit as of December 30, 2011 and December 31, 2010 (approximately $2.4 million based on the foreign exchange rates on December 28, 2012), and increased its amount outstanding on the line of credit to 500,000,000 Yen (approximately $5.9 million based on the exchange rate on December 28, 2012) on December 28, 2012. In 2012, the Company paid approximately $65,000 in interest expense related to its borrowings from Mizuho and the Company expects its interest expense on the bank line to remain approximately the same in 2013. While there are no assurances, the Company believes the credit line will be renewed in fiscal 2013, similar to the renewals that have occurred since 2007.

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	
	December 28, 2012	December 30, 2011	December 31, 2010	2012 vs. 2011	2011 vs. 2010
Net sales	100.0%	100.0%	100.0%	1.6%	14.2%
Cost of sales	30.6%	32.5%	36.2%	(4.4)%	2.6%
Gross profit	69.4%	67.5%	63.8%	4.5%	20.8%
General and administrative	23.7%	23.8%	26.9%	1.5%	6.1%
Marketing and selling	33.4%	28.2%	31.3%	20.1%	3.2%
Research and development	10.1%	9.3%	10.4%	9.8%	2.5%
Other general and administrative expenses	4.1%	1.7%	—	*	—
Operating income (loss)	(1.9)%	4.4%	(4.7)%	*	— *
Total other expense, net	1.1%	(0.1)%	(2.0)%	*	(92.7)%
Income (loss) before income taxes	(0.8)%	4.3%	(6.7)%	*	— *
Provision for income taxes	2.0%	2.2%	0.8%	(8.3)%	— *
Income (loss) from continuing operations	(2.8)%	2.1%	(7.5)%	*	— *
Income from discontinued operations, net of income taxes	0.0%	0.0%	7.6%	0.0%	— *
Net income (loss)	(2.8)%	2.1%	0.1%	*	— *

* Denotes change is greater than 100%

The following table presents our net sales, by product, for the fiscal years presented (dollars in thousands):

	% of Total	2012	% of Total	2011	% of Total	2010
IOL	40.7 %	$25,971	43.9 %	$27,547	50.1 %	$27,550
ICL	55.0 %	35,080	51.1 %	32,074	44.2 %	24,300
Core Product Sales	95.7 %	61,051	95.0 %	59,621	94.3 %	51,850
Other	4.3 %	2,732	5.0 %	3,144	5.7 %	3,108
Total Sales	100.0%	$63,783	100.0%	$62,765	100.0%	$54,958

Net sales for 2012 were $63.8 million, a 1.6% increase over the $62.8 million reported in fiscal 2011. The increase in net sales was due to a 9.4% increase in ICL sales, which was largely offset by a 5.7% decrease in IOL sales and a 13.2% decrease in other product sales. Changes in foreign currency did not materially impact our net sales for the year.

Net sales for 2011 were $62.8 million, a 14.2% increase over the $55.0 million reported in fiscal 2010. The increase in net sales was due to 15% increase in our core product sales (IOL and ICL). Core products represented 95.0% and 94.3% of the Company’s total sales in fiscal year 2011 and 2010, respectively. Changes in foreign currency favorably impacted our net sales in 2011 by $1.7 million.

Total IOL sales were $26.0 million for fiscal 2012, a 5.7% decrease from fiscal 2011 sales of $27.5 million. The primary reason for the decrease was a 25% decrease in U.S. IOL sales volume. The effect of the decrease in unit volume was partially offset by an 11% increase in average selling prices. Preloaded IOL sales in international markets decreased 1%, despite a 5% increase in unit volume, because of a 6% decline in average selling prices due to a mix shift to Preloaded Acrylic IOLs which have lower average selling prices than most other IOL models. IOL sales represented 41% of the Company’s total sales in fiscal 2012. Preloaded IOL sales represented 76% of total IOL sales in fiscal 2012.

Total IOL sales were $27.5 million for fiscal 2011 and 2010, respectively. Increased sales of preloaded acrylic IOLs in China and Germany and Toric IOLs in the U.S. were offset by decreased Collamer and silicone IOL sales. Although IOL sales were essentially flat year over year, IOL margins were up 3% due to improved average selling prices, costs, and geographic mix. As an example, sales of our largest selling IOL, the Preloaded silicone IOL, were down 1% year over year. However, Preloaded IOL gross profit was up 3% due to higher sales in Japan where margins are high and lower sales in Europe where margins are low. IOL sales represented 43.9% and 50.1% of the Company’s total sales in fiscal 2011 and 2010, respectively. Preloaded IOL sales represented 72% of total IOL sales in fiscal 2011, compared with 69% in fiscal 2010.

Total ICL sales for 2012 were $35.1 million, a 9.4% increase over the $32.1 million in fiscal 2011. Unit volume increased 3% and average selling prices increased 6%. ICL sales growth was lower than anticipated due to an 18% decrease in ICL sales in Korea as the distributor adjusted its inventories levels. Outside of Korea, ICL sales grew 18%. The Company expects that ICL sales in Korea will return to growth in 2013. ICL sales represented 55% of our total sales for fiscal 2012. Toric ICL sales represented 49% of total ICL sales, where approved.

Total ICL sales for 2011 were $32.1 million, a 32% increase over the $24.3 million reported in fiscal 2010. The increase in ICL sales resulted from a 35% increase in sales in our then top ten refractive markets which comprised 85% of our total ICL sales in 2011. ICL sales represented 51% and 44% our total sales for fiscal years 2011 and 2010, respectively. Toric ICL sales represented 44% of total ICL sales, where approved, compared with 43% in fiscal 2010.

Other product sales, which have been deemphasized due to their low margins, were $2.7 million in fiscal 2012 and $3.1 million in fiscal 2011. Other product sales represented 4.3% and 5.0% of the Company's total sales in fiscal 2012 and 2011, respectively.

The following table presents our gross profit and gross profit margin for the fiscal years presented (dollars in thousands):

	2012	2011	2010
Gross Profit	$44,291	$42,369	$35,076
Gross Profit Margin	69.4 %	67.5 %	63.8 %

Gross profit in fiscal 2012 was $44.3 million compared with $42.4 million in fiscal 2011. The increase in gross profit and gross profit margin was largely attributable to the 9% increase in ICL sales and more specifically Toric ICLs, that have higher average selling prices, which grew 22%. Gross profit in fiscal 2011 was $42.4 million compared with $35.1 million in fiscal 2010. The increase in gross profit and gross profit margin was largely attributable to a higher mix of ICL sales and improved margins on IOL sales.

The following table presents our general and administrative expense for the fiscal years presented (dollars in thousands):

	2012	2011	2010
General and Administrative Expense	$15,150	$14,932	$14,778
Percentage of Sales	23.7 %	23.8 %	26.9 %

General and administrative (G&A) expense in fiscal 2012 was $15.1 million or 23.7% of sales, compared with $14.9 or 23.8% of sales in fiscal 2011. Although G&A expense has decreased as a percentage of sales, the increase in dollars was primarily due to an increase in stock based compensation expense.

General and administrative expense in fiscal 2011 was $14.9 million or 23.8% of sales, compared with $14.8 million or 26.9% of sales in fiscal 2010. The increase in expense was primarily due to increased bonus accruals, travel and stock based compensation expense largely offset by a $700,000 decrease in severance costs.

The following table presents our marketing and selling expense for the fiscal years presented (dollars in thousands):

	2012		2011		2010	
Marketing and Selling Expense	$21,281		$17,726		$17,176	
Percentage of Sales	33.4	%	28.2	%	31.3	%

Marketing and selling expense in fiscal 2012 was $21.3 million or 33.4% of sales, compared with $17.7 or 28.2% of sales in fiscal 2011. The increase in sales and marketing expense was due to the addition of 17 employees during 2012 to support the Company's ICL growth initiatives in Asia Pacific, Europe, and the U.S. and to support global marketing efforts.

Marketing and selling expense in fiscal 2011 was $17.7 million or 28.2% of sales, compared with $17.2 million or 31.3% of sales in fiscal 2010. The increase in marketing and selling expense was due to increased headcount to support sales growth internationally and increased global promotional costs, partially offset by decreased costs in Australia resulting from the transition of the business to an independent distribution model.

The following table presents our research and development expense for the fiscal years presented (dollars in thousands):

	2012		2011		2010	
Research and Development Expense	$6,444		$5,868		$5,724	
Percentage of Sales	10.1	%	9.3	%	10.4	%

Research and development expenses consist primarily of compensation and related costs for personnel responsible for the research and development of new and existing products and the regulatory and clinical activities required to acquire and maintain product approvals globally. These costs are expensed as incurred.

Research and development expense in fiscal 2012 was $6.4 million or 10.1% of sales, compared with $5.9 million or 9.3% of sales in fiscal 2011. The increase in expense is due to an increase in compensation costs, including stock-based compensation and due to new product development activities. The Company expects to spend approximately 9-10% of sales on research and development activities in 2013.

Research and development expense in fiscal 2011 was $5.9 million or 9.3% of sales, compared with $5.7 million or 10.4% of sales in fiscal 2010. The increase in expense is due to increased headcount and salaries, travel, and patent legal expenses.

The following table presents other general and administrative expenses for the fiscal years presented (dollars in thousands):

	2012	2011	2010
Other General and Administrative Expenses	$2,636	$1,060	—
Percentage of Sales	4.1 %	1.7 %	—

Other general and administrative expenses in fiscal 2012 of $2.6 million compared with $1.1 million in fiscal 2011 represent costs associated with the Company's plans to consolidate its manufacturing operations. This expense was higher than originally planned for the year due to a change in the timing of severance accruals. Overall the project is still expected to be completed generally on budget and on time. The Company expects to spend approximately $2.0 to $2.5 million on the project during 2013.

Other general and administrative expenses in fiscal 2011 of $1.1 million represent costs associated with the Company's plans to consolidate the manufacturing operations currently conducted in Switzerland, Japan, and Aliso Viejo, California, into its Monrovia, California location. These costs include consulting and tax services, accruals for asset retirement obligations, severance, and certain employee costs, including travel. The total cost of the project is expected to total approximately $6 million and recorded over a four year period beginning 2011. Capital costs associated with the project are expected to total approximately $2.4 million.

The following table presents our other income (expense), net for the fiscal years presented (dollars in thousands):

	2012	2011	2010
Other Income (Expense), net	$701	$(79)	$(1,079)
Percentage of Sales	1.1%	(0.1)%	(2.0)%

Other income (expense), net generally relates to interest expense on notes payable and lease obligations, gains or losses on foreign currency transactions, royalty income, and fair value adjustments of outstanding warrants. The table below summarizes the year over year changes in other income (expense), net (in thousands).

	Favorable (Unfavorable)	
	2012 v. 2011	2011 v. 2010
Interest income	$ 27	$ (12)
Interest expense	232 (3)	373 (1)
Loss on extinguishment of note payable	-	267 (1)
Exchange gains (losses)	25	173
Royalty income	(58)	137
Fair value adjustment of warrants[2]	452	25
Other	102 (4)	35
Net change in other income (expense), net	$ 780	$ 1,000

(1) The decrease in interest expense was primarily due to the repayment of the Broadwood note in fiscal 2010. The loss on early extinguishment of note payable was the result of early repayment of the Broadwood note.

(2) Relates to the fair value of 70,000 warrants issued to Broadwood on March 21, 2007 at $6.00 per share. The warrants expire on March 21, 2013.

(3) Decrease in interest expense is due to the fulfillment of certain capital lease obligations.

(4) Other income resulted from the release of restricted cash which was set aside for the payment of potential taxes of our former German subsidiary.

The following table presents our provision for income taxes for the fiscal years presented (in thousands):

	2012	2011	2010
Provision for Income Taxes	$1,244	$1,356	$432

The provision for income taxes decreased from 2011 to 2012, as a result of decrease in income in jurisdictions where we pay taxes. We do not expect to begin to see the tax benefits associated with our manufacturing consolidation project until 2014 when manufacturing is projected to be fully consolidated.

Our provision for income taxes increased from 2011 to 2010, as a result of higher taxable income in jurisdictions where we pay tax. Our effective tax rate for 2011 was 50%.

See Critical Accounting Policies included later in this Item 7 for additional information about our provision for income taxes.

A reconciliation of the federal statutory income tax rate to our effective tax rate is set forth in Note 11 of Notes to the Consolidated Financial Statements included in Item 8 of this Annual Report on Form 10-K.

Liquidity and Capital Resources

We have historically financed our operations primarily through operating cash flows, the issuance of common stock and proceeds from stock options and by relying on equipment and other commercial financing. During 2013, and for the foreseeable future, we will be highly dependent on our net product revenue to supplement our current liquidity and

fund our operations. We may, in the future elect, to supplement this with further debt or commercial borrowing

The Company believes its current cash balances coupled with cash flow from operating activities will be sufficient to meet its working capital requirements for the foreseeable future, including cost and capital associated with the Company's plans to consolidate manufacturing. 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 maintaining positive cash flow through the strategies described above under the caption "Strategy."

Our financial condition as of December 28, 2012 for each of the years indicated included the following (in millions):

	2012	2011	2010	2012 v. 2011	2011 v. 2010
Cash and cash equivalents	$21.7	$16.6	$9.4	$ 5.1	$ 7.2
Current assets	$44.1	$38.7	$30.0	$ 5.4	$ 8.7
Current liabilities	17.9	14.0	13.4	3.9	0.6
Working capital	$26.2	$24.7	$16.6	$ 1.5	$ 8.1

Overview of changes in cash and cash equivalents and other working capital accounts.

Net cash provided by (used in) operating activities was $3.2 million, $5.3 million, and ($4.4 million) for fiscal years 2012, 2011, and 2010 respectively. For 2012, net cash provided by operating activities consisted of net loss of $1.8 million, $5.4 million in non-cash expenses and $0.4 million used for working capital. For 2011, net cash provided by operating activities consisted of net income of $1.3 million, $4.6 million in non-cash expenses and $0.6 million used for working capital. For 2010, the use of cash from operations included the following significant items: payment of $4.0 million related to the global settlement of the legal judgments and $0.6 million used in the operating activities of discontinued operations of our previously disposed German subsidiary Domilens GmbH, payment of $0.4 million of Domilens transaction related costs, and approximately $0.8 million interest paid for the Broadwood note.

Net cash provided by (used in) investing activities was ($2.1 million), ($0.9 million), and $18.8 million for fiscal years 2012, 2011, and 2010 respectively. Net cash used in investing activities for 2012 and 2011 was due to acquisition of property, plant and equipment. The increase in investment in property, plant, and equipment during 2012, relative to 2011, is due to investments made in connection with the Company's plans to consolidate its manufacturing operations to the U.S. and leasehold improvements related to the expansion of the Company's Monrovia, CA facility. For 2010, net cash provided by investing activities was due to the $11.8 million net cash proceeds from the sale of Domilens in March 2010 and the release of the $7.4 million restricted deposit, including interest, by the Court, partially offset by $0.4 million for acquisition of property and equipment.

Net cash provided by (used by) financing activities was $4.3 million, $2.8 million, and ($11.5 million) for fiscal years 2012, 2011 and 2010, respectively. For 2012, net cash provided by financing activities consisted of $3.5 million increase in line of credit and $1.5 million in proceeds from exercise of stock options, partially offset by $0.7 million in capital lease repayments. For 2011, net cash provided by financing activities consisted of $3.3 million in proceeds from exercise of stock options, partially offset by $0.6 million in capital lease repayments. For 2010, net cash used by financing activities consisted of $5 million principal payment on a promissory note held by Broadwood Partners, L.P., the $6.8 million cash redemption of all of our then outstanding Series A preferred shares, and the $0.8 million repayment of principal on our capital lease obligations, partially offset by $1.1 million in cash proceeds from stock option exercises

Accounts receivable was $8.5 million as of December 28, 2012 and $9.1 million as of December 30, 2011. Days' Sales Outstanding ("DSO") was 47 days in 2012 and 50 days in 2011. The Company expects to maintain DSO within a range of 45 to 50 days during the course of fiscal 2013.

Inventories at the end of fiscal 2012 and 2011 were $11.7 million and $10.9 million, respectively. Days' inventory on hand ("DOH") was 142 days in 2012 and 129 days in 2011 based on finished goods, including consignment inventory. We planned for this increase to provide safety stock during our manufacturing consolidation project.

Shelf Registration

In August 2011, STAAR filed a universal "shelf registration statement" with the Securities and Exchange Commission. The shelf registration statement covers the future public offering and sale of up to $75 million in equity or debt securities or any combination of such securities. STAAR currently has no plans to issue any securities under the shelf registration statement. Among the purposes for which STAAR could use the proceeds of securities sold in the future under the shelf registration statement are working capital, capital expenditures, expansion of sales and marketing, and continuing research and development. STAAR could also use a portion of the net proceeds to acquire or invest in businesses, assets, products and technologies that are complementary to our own, although we are not currently contemplating or negotiating any such acquisitions or investments. The availability of financing in the public capital markets through the shelf registration statement depends on a number of factors in place at the time of financing,

including the strength of STAAR's business performance, general economic conditions and investment climate, and investor perceptions of those factors. If STAAR seeks financing under the shelf registration statement in the future, we cannot assure that such financing will be available on favorable terms, if at all.

Credit Facilities, Contractual Obligations and Commitments

Credit Facilities

The Company has credit facilities with different lenders to support operations as detailed below.

Line of Credit

The Company's wholly owned Japanese subsidiary, STAAR Japan, has an agreement, as amended on December 28, 2012, with Mizuho Bank which provides for borrowings of up to 500,000,000 Yen (approximately $5.8 million based on the rate of exchange on December 28, 2012), at an interest rate equal to the Tokyo short-term prime interest rate (approximately 1.475% as of December 28, 2012) and may be renewed annually (the current line expires on March 28, 2013). The credit facility is not collateralized. In case of default, the interest rate will be increased to 14% per annum. While no assurance can be given, the Company believes the credit line will be renewed in fiscal 2013. The Company had 500,000,000 Yen and 200,000,000 Yen outstanding on the line of credit as of December 28, 2012 and December 30, 2011, (approximately $5.8 million and $2.6 million based on the foreign exchange rates on December 28, 2012 and December 30, 2011, respectively) which approximates fair value due to the short-term maturity and market interest rates of the line of credit. As of December 28, 2012, there were no available borrowings under the line.

In August 2010, the Company's wholly owned Swiss subsidiary, STAAR Surgical AG, entered into a credit agreement with Credit Suisse (the Bank). The credit agreement provides for borrowings of up to 1,000,000 CHF (Swiss Francs) ($1,096,000 at the rate of exchange on December 28, 2012), to be used for working capital purposes. Accrued interest and 0.25% commissions on average outstanding borrowings is payable quarterly and the interest rate will be determined by the Bank based on the then prevailing market conditions at the time of borrowing. The credit agreement is automatically renewed on an annual basis based on the same terms assuming there is no default. The credit agreement may be terminated by either party at any time in accordance with its general terms and conditions. The credit facility is not collateralized and contains certain conditions such as providing the Bank with audited financial statements annually and notice of significant events or conditions as defined in the credit agreement. The Bank may also declare all amounts outstanding to be immediately due and payable upon a change of control or a "material qualification" in STAAR Surgical AG's independent auditors' report. There were no borrowings outstanding as of December 28, 2012 and the full amount of the line was available for borrowing.

Covenant Compliance

The Company is in compliance with the covenants of its credit facilities and lines of credit as of December 28, 2012.

Contractual Obligations

The following table represents the Company's known contractual obligations as of December 28, 2012 (in thousands):

	Payments Due by Period				
Contractual Obligations	Total	1 Year	**2-3 Years**	**4-5 Years**	**More Than 5 Years**
Line of credit	$5,850	$5,850	$—	$—	$ —
Capital lease obligations	1,394	916	470	8	—
Operating lease obligations	8,445	2,408	3,608	1,744	685
Pension obligation	1,507	110	234	439	724
Severance	1,010	102	908	—	—
Open purchase orders	423	423	—	—	—
Total	$18,629	$9,809	$5,220	$2,191	$ 1,409

Critical Accounting Policies

The preparation of financial statements in accordance with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of sales and expenses during the reporting period. On an on-going basis, we evaluate our estimates, including those related to revenue recognition, allowances for doubtful accounts and sales return, inventory reserves and income taxes, among others. Our estimates are based on historical experiences, market trends and financial forecasts and projections, and on various other assumptions that management believes are reasonable under the circumstances and at that certain point in time. Actual results may differ, significantly at times, from these if actual conditions differ from our assumptions.

We believe the following represent our critical accounting policies.

Revenue Recognition and Accounts Receivable. We recognize revenue when realized or realizable and earned, which is when the following criteria are met: persuasive evidence of an arrangement exists; delivery has occurred; the sale price is fixed and determinable; and collectability is reasonably assured. The Company records revenue from non-consignment product sales when title and risk of ownership has been transferred, which is typically at shipping point, except for our STAAR Japan subsidiary, which is typically recognized when the product is received by the customer. STAAR Japan does not have significant deferred revenues as delivery to the customer is generally made within the same or the next date of shipment. Our products are marketed to ophthalmic surgeons, hospitals, ambulatory surgery centers or vision centers, and distributors. IOLs may be offered to surgeons and hospitals on a consignment basis. We maintain title and risk of loss on consigned inventory. We recognize revenue for consignment inventory when we are informed the IOL has been implanted and not upon shipment to the surgeon. We believe our revenue recognition policies are appropriate. We present sales tax we collect from our customers on a net basis (excluded from our revenues).

We ship ICLs only for use by surgeons who have already been certified, or for use in scheduled training surgeries.

For all sales, we are the principal in the transaction as we, among other factors, bear general inventory risk, credit risk, have latitude in establishing the sales price and bear authorized sales returns inventory risk. Therefore, sales are recognized gross with corresponding cost of sales in the statement of operations instead of a single, net amount. Cost of sales includes cost of production, freight and distribution, royalties, and inventory provisions, net of any purchase discounts.

We generally permit returns of product if the product is returned within the time allowed by our return policies, and in good condition. We provide allowances for sales returns based on an analysis of our historical patterns of returns matched against the sales from which they originated. While such allowances have historically been within our expectations, we cannot guarantee that we will continue to experience the same return rates that we have in the past. Measurement of such returns requires consideration of, among other factors, historical returns experience and trends, including the need to adjust for current conditions and product lines, the entry of a competitor, and judgments about the probable effects of relevant observable data. We consider all available information in our quarterly assessments of the adequacy of the allowance for sales returns. Sales are reported net of estimated returns. If the actual sales returns are higher or lower than estimated by management, additional reduction or increase in sales may occur.

We maintain provisions for uncollectible accounts based on estimated losses resulting from the inability of our customers to remit payments. If the financial condition of customers were to deteriorate, thereby resulting in an inability to make payments, additional allowances could be required. We perform ongoing credit evaluations of our customers and adjust credit limits based upon customer payment history and current creditworthiness, as determined by our review of our customers' current credit information. We continuously monitor collections and payments from our customers and maintain a provision for estimated credit losses based upon our historical experience and any specific customer collection issues that have been identified. We write off amounts determined to be uncollectible against the allowance for doubtful accounts. While such credit losses have historically been within our expectations and the provisions established, we cannot guarantee that we will continue to experience the same credit loss rates that we have in the past. Measurement of such losses requires consideration of historical loss experience, including the need to adjust for current conditions, and judgments about the probable effects of relevant observable data, including present economic conditions such as delinquency rates and financial health of specific customers. We consider all available information in our assessments of the adequacy of the reserves for uncollectible accounts.

Stock-Based Compensation. We account for the issuance of stock options to employees and directors by estimating the fair value of options and warrants issued using the Black-Scholes pricing model. This model's calculations include the exercise price, the market price of shares on grant date, risk-free interest rates, expected term of the option or warrant, expected volatility of our stock and expected dividend yield. The amounts recorded in the financial statements for share-based expense could vary significantly if we were to use different assumptions.

- *Accounting for Warrants.* We account for the issuance of company derivative equity instruments such as the warrants, in accordance with ASC 815-40. We agreed to use our best efforts to register and maintain registration of the common shares underlying certain warrants (the "Warrant Shares") that were issued by us with debt instruments, so that the warrant holder may freely sell the Warrant Shares if the warrant is exercised, and we agreed that in any

event we would secure effective registration within a certain time period after issuance (typically up to five months from issuance). In addition, while the relevant warrant agreement does not require cash settlement if we do not maintain continuous registration of certain Warrant Shares, the agreement does not specifically preclude cash settlement. As a result ASC 815-40 requires us to assume that in the absence of continuous effective registration we may be required to settle some of these warrants for cash when they are exercised. Accordingly, our agreement to register and maintain registration of certain Warrant Shares without express terms for settlement in the absence of continuous effective registration is presumed to create a liability to settle these warrants in cash, requiring liability classification. We have issued other warrants under another agreement that expressly provides that if we fail to satisfy registration requirements we will be obligated only to issue additional common stock as the holder’s sole remedy, with no possibility of settlement in cash. In this circumstance, we account for those warrants as equity because additional shares are the only form of settlement available to the holder. We use the Black-Scholes option pricing model as the valuation model to estimate the fair value of all warrants. We evaluate the balance sheet classification of the warrants during each reporting period. Expected volatilities are based on historical volatility of our stock. The expected life of the warrant is determined by the amount of time remaining on the original six-year term of the relevant warrant agreement. The risk-free rate of return for periods within the contractual life of the warrant is based on the U.S. Treasury yield curve in effect at each reporting period. Any gains or losses resulting from the changes in fair value of the warrants classified as a liability from period to period are included as an increase or decrease of other income (expense). The warrants that are accounted for as equity are only valued on the issuance date and not subsequently revalued.

Income Taxes. We account for income taxes under the asset and liability method, whereby deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. We evaluate the need to establish a valuation allowance for deferred tax assets based on the amount of existing temporary differences, the period in which they are expected to be recovered and expected levels of taxable income. A valuation allowance to reduce deferred tax assets is established when it is "more likely than not" that some or all of the deferred tax assets will not be realized.

We expect to continue to maintain a full valuation allowance on future tax benefits until, and if, an appropriate level of profitability is sustained, or we are able to develop tax strategies that would enable us to conclude that it is more likely than not that a portion of our deferred tax assets would be realizable.

In the normal course of business, the Company is regularly audited by federal, state and foreign tax authorities, and is periodically questioned regarding the amount of taxes due. These questions may relate to the timing and amount of deductions and the allocation of income among various tax jurisdictions. We believe that our tax positions comply with applicable tax law and intend to defend our positions, if necessary. Our effective tax rate in a given financial statement period could be impacted if we prevailed in matters for which reserves have been established, or were required to pay amounts in excess of established reserves.

Inventories. We provide estimated inventory allowances for excess, slow moving, expiring and obsolete inventory as well as inventory whose carrying value is in excess of net realizable value. These reserves are based on current assessments about future demands, market conditions and related management initiatives. If market conditions and actual demands are less favorable than those projected by management, additional inventory write-downs may be required. We value our inventory at the lower of cost or net realizable market values. We regularly review inventory quantities on hand and record a provision for excess and obsolete inventory based primarily on the expiration of products with a shelf life of less than four months, estimated forecasts of product demand and production requirements for the next twelve months. Several factors may influence the realizability of our inventories, including decisions to exit a product line, technological change and new product development. These factors could result in an increase in the amount of obsolete inventory quantities on hand. Additionally, estimates of future product demand may prove to be inaccurate, in which case the provision required for excess and obsolete inventory may be understated or overstated. If in the future, we determine that our inventory was overvalued, we would be required to recognize such costs in cost of sales at the time of such determination. Likewise, if we determine that our inventory was undervalued, cost of sales in previous periods could have been overstated and we would be required to recognize such additional operating income at the time of sale. While such inventory losses have historically been within our expectations and the provisions established, we cannot guarantee that we will continue to experience the same loss rates that we have in the past. Therefore, although we make every effort to ensure the accuracy of forecasts of future product demand, including the impact of planned future product launches, any significant unanticipated changes in demand or technological developments could have a significant impact on the value of our inventory and our reported operating results.

- *Impairment of Long-Lived Assets.* Intangible and other long lived-assets are reviewed for impairment whenever events such as product discontinuance, plant closures, product dispositions or other changes in circumstances

indicate that the carrying amount may not be recoverable. Certain factors which may occur and indicate that an impairment exists include, but are not limited to the following: significant underperformance relative to expected historical or projected future operating results; significant changes in the manner of the Company's use of the underlying assets; and significant adverse industry or market economic trends. In reviewing for impairment, we compare the carrying value of such assets to the estimated undiscounted future net cash flows expected from the use of the assets and their eventual disposition. In the event that the carrying value of assets is determined to be unrecoverable, we would estimate the fair value of the assets and record an impairment charge for the excess of the carrying value over the fair value. The estimate of fair value requires management to make a number of assumptions and projections, which could include, but would not be limited to, future revenues, earnings and the probability of certain outcomes and scenarios. Our policy is consistent with current accounting guidance as prescribed by ASC 360-10-35, *Accounting for the Impairment or Disposal of Long-Lived Assets.*

Goodwill. Goodwill, which has an indefinite life, is not amortized, but instead is subject to periodic testing for impairment. Intangible assets determined to have definite lives are amortized over their remaining useful lives. Goodwill is tested for impairment on an annual basis or between annual tests if an event occurs or circumstances change that would reduce the fair value of a reporting unit below its carrying amount. Certain factors which may occur and indicate that impairment exists include, but are not limited to the following: significant underperformance relative to expected historical or projected future operating results; significant changes in the manner of our use of the underlying assets; and significant adverse industry or market economic trends. In the event that the carrying value of assets is determined to be unrecoverable, we would estimate the fair value of the reporting unit and record an impairment charge for the excess of the carrying value over the fair value. The estimate of fair value requires management to make a number of assumptions and projections, which could include, but would not be limited to, future revenues, earnings and the probability of certain outcomes and scenarios, including the use of experts.

Definite-Lived Intangible Assets. We also have other intangible assets mainly consisting of patents and licenses, developed technologies and customer relationships, with a gross book value of $13.8 million and accumulated amortization of $11.6 million as of December 28, 2012. We capitalize the cost of acquiring patents and licenses. We acquired certain customer relationships and developed technologies in the acquisition of our STAAR Japan subsidiary which was completed on December 29, 2007. Amortization is computed on the straight-line basis over the estimated useful lives of the assets, since the pattern in which the economic benefits realized cannot be reasonably determined, which are based on legal, contractual and other provisions, and range from 10 to 21 years for patents and licenses, 10 years for customer relationships and 3 to 10 years for developed technology. We review intangible assets for impairment in the assessment discussed above regarding *Impairment of Long-Lived Assets.*

Employee Defined Benefit Plans. We have maintained a passive pension plan (the “Swiss Plan”) covering employees of its Swiss subsidiary. The Company concluded that the features of the Swiss Plan conform to the features of a defined benefit plan. As a result, we adopted the recognition and disclosure requirements of Accounting Standards Codification Transition Guidance, Employers’ Accounting for Defined Benefit Pension and Other Postretirement Plans.

In connection with our acquisition of the remaining interest in STAAR Japan, Inc., we assumed the net pension liability under STAAR Japan’s noncontributory defined benefit pension plan substantially covering all of the employees of STAAR Japan. STAAR Japan adopted the recognition and disclosure requirements of Accounting Standards Codification for *Defined Benefit Plans - Pension* on December 29, 2007, the date of the acquisition.

Defined Benefits Plans - Pension requires recognition of the funded status, or difference between the fair value of plan assets and the projected benefit obligations of the pension plan on the statement of financial position with a corresponding adjustment to accumulated other comprehensive income. If the projected benefit obligation exceeds the fair value of plan assets, then that difference or unfunded status represents the pension liability. We record a net periodic pension cost in the consolidated statement of operations. The liabilities and annual income or expense of both plans are determined using methodologies that involve several actuarial assumptions, the most significant of which are the discount rate, and the expected long-term rate of asset return (based on the market-related value of assets). The fair values of plan assets are determined based on prevailing market prices. The amounts recorded in the financial statements pertaining to our employee defined benefit plans could vary significantly if we were to use different assumptions.

Foreign Exchange

Management does not believe that the fluctuation in the value of the dollar in relation to the currencies of its suppliers or customers in the last three fiscal years had adversely affected our ability to purchase or sell products at agreed upon prices. No assurance can be given, however, that adverse currency exchange rate fluctuations will not occur in the future, which could significantly affect our operating results. We do not engage in hedging transactions to offset changes in currency or fluctuations in foreign currencies.

Inflation

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

Recent Accounting Pronouncements

See Item 8 of Part II, "Financial Statements and Supplementary Data – Note 1 – Organization and Description of Business and Accounting Policies – Recent Accounting Pronouncements."

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

In the normal course of business, our operations are exposed to risks associated with fluctuations in interest rates and foreign currency exchange rates. The Company manages its risks based on management's judgment of the appropriate trade-off between risks, opportunity, and costs and does not generally enter into interest rate or foreign exchange rate hedge instruments.

Interest rate risk. As of December 28, 2012, STAAR had $5.9 million of foreign debt. Our $5.9 million of foreign debt bears an interest rate that is equal to the Tokyo short-term prime interest rate (approximately 1.475% as of December 28, 2012). Thus, our interest expense would fluctuate with any change in the prime interest rate. If the Tokyo prime rate were to increase or decrease by 1% for the year, our annual interest expense would increase or decrease by approximately $59,000 based on the exchange rate in effect at December 28, 2012.

Foreign currency risk. Fluctuations in the rate of exchange between the U.S. dollar and foreign currencies in which we transact business could adversely affect our financial results. Cost of goods sold and selling, general, and administrative expenses that correspond with these sales are largely denominated in the same currency, thereby limiting our transaction risk exposure.

Our international subsidiaries operate in and are net recipients of currencies other than the U.S. dollar and, as a result, our sales benefit from a weaker dollar and are reduced by a stronger dollar relative to major currencies worldwide (primarily, the Euro and the Japanese Yen). Accordingly, changes in exchange rates, and particularly the strengthening of the U.S. Dollar, may negatively affect our consolidated sales and gross profit as expressed in U.S. dollars. Additionally, expenses of our Swiss subsidiary are largely denominated in Swiss Francs and a strong Swiss

Franc negatively impacts our earnings. Fluctuations during any given reporting period result in the re-measurement of our foreign currency denominated cash, receivables, and payables, generating currency transaction gains or losses and are reported in total other expenses in our consolidated statements of operations. In the normal course of business, we also face risks that are either non-financial or non-quantifiable. Such risks include those set forth in "Item 1A. — Risk Factors."

Item 8. Financial Statements and Supplementary Data

Financial Statements and the Reports of Independent Registered Public Accounting Firm are filed with this Annual Report on Form 10-K in a separate section following Part IV, as shown on the index under Item 15 of this Annual Report.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

Item 9A. Controls and Procedures

Attached as exhibits to this Annual Report on Form 10-K are certifications of STAAR's Chief Executive Officer ("CEO") and Chief Financial Officer ("CFO"), which are required in accordance with Rule 13a-14 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). This "Controls and Procedures" section includes information concerning the controls and controls evaluation referred to in the certifications. Page F-3 of this Annual Report on Form 10-K sets forth the report of BDO USA, LLP, our independent registered public accounting firm, regarding its audit of STAAR's internal control over financial reporting. This section should be read in conjunction with the certifications and the BDO USA, LLP report for a more complete understanding of the topics presented.

Evaluation of Disclosure Controls and Procedures

As of the end of the period covered by this report, we carried out an evaluation, under the supervision and with the participation of our management, including our CEO and CFO, of the effectiveness of the design and operation of the disclosure controls and procedures of the Company. Based on that evaluation, our CEO and CFO concluded, as of the end of the period covered by our Form 10-K for the fiscal year ended December 28, 2012, that our disclosure controls and procedures were effective. For purposes of this statement, the term “disclosure controls and procedures” means controls and other procedures of the Company that are designed to ensure that information required to be disclosed by the Company in the reports that it files or submits under the Securities Exchange Act (15 U.S.C. 78a et seq) is recorded, processed, summarized and reported, within the time periods specified in the Commission's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by the issuer in the reports that it files or submits under the Act is accumulated and communicated to the issuer's management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

Management’s Annual Report on Internal Control over Financial Reporting

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

Because of its inherent limitations, a system of internal control over financial reporting can provide only reasonable assurance and may not prevent or detect misstatements. Further, because of changing conditions, effectiveness of internal control over financial reporting may vary over time. The Company’s processes contain self-monitoring mechanisms, and actions are taken to correct deficiencies as they are identified.

Management has assessed the effectiveness of the Company’s internal control over financial reporting as of December 28, 2012, based on the criteria for effective internal control described in Internal Control — Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on its assessment, management concluded that the Company’s internal control over financial reporting was effective as of December 28, 2012.

Changes in Internal Control over Financial Reporting

There was no change during the fiscal quarter ended December 28, 2012 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

Pursuant to our Amended and Restated 2003 Omnibus Equity Incentive Plan, our Compensation Committee approved the performance goals and the amount of compensation for a 2013 Restricted Stock Unit Plan ("2013 RSU Plan"), which is a performance contingent restricted stock award plan based upon the Company exceeding an internally established annual revenue target which is above the established annual revenue plan. This plan was ratified by the Board of Directors of STAAR Surgical Company on March 4, 2013, contingent upon acceptance by the participants, which was obtained on March 12, 2013. The Chief Executive Officer, Chief Financial Officer and named Executive Officers participate in the ("2013 RSU Plan"). The equity grant under the 2013 RSU Plan occurs if the Company meets or exceeds 100% of an internally established annual sales target, at which point participants would receive their potential grant. The maximum potential grant for the Chief Executive Officer is 30,000 shares; for the Chief Financial Officer is 6,500 shares; for the Vice President, Global Marketing is 12,000 shares; for the Vice President, Global Research and Development is 7,500 shares, for the President of EMEA and Latin America is 12,000 shares; for the Vice President, Swiss Operations is 5,000 shares, and for the Vice President, General Counsel is 5,000 shares. Any shares granted under the 2013 RSU Plan vest after calculating total financial performance in 2013, at which time, if the revenue target is met or exceeded, the earned shares shall fully vest.

PART III

Item 10. Directors and Executive Officers and Corporate Governance

The information required by this item is incorporated herein by reference to the section entitled “Proposal One — Election of Directors” contained in the proxy statement (the “Proxy Statement”) for the 2013 annual meeting of stockholders to be filed with the Securities and Exchange Commission within 120 days of the close of the fiscal year ended December 28, 2012.

Item 11. Executive Compensation

The information required by this item is incorporated herein by reference to the section entitled “Proposal One — Election of Directors” contained in the Proxy Statement.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The information required by this item is incorporated herein by reference to the section entitled “General Information — Security Ownership of Certain Beneficial Owners and Management” and “Proposal One — Election of Directors” contained in the Proxy Statement.

Item 13. Certain Relationships and Related Transactions and Director Independence

The information required by this item is incorporated herein by reference to the section entitled “Proposal One — Election of Directors” contained in the Proxy Statement.

Item 14. Principal Accountant Fees and Services

The information required by this item is incorporated herein by reference to the section entitled “Proposal Three — Ratification of the Appointment of Independent Registered Public Accounting Firm” contained in the Proxy Statement.

PART IV

Item 15. Exhibits and Financial Statement Schedules

We have filed the following documents as part of this Annual Report on Form 10-K:	**Page**
(1) Consolidated Financial Statements	
Reports of Independent Registered Public Accounting Firm	F-2
Consolidated Balance Sheets	F-4
Consolidated Statements of Operations	F-5
Consolidated Statements of Comprehensive Income (Loss)	F-6
Consolidated Statements of Changes in Stockholders' Equity	F-7
Consolidated Statements of Cash Flows	F-8
Notes to Consolidated Financial Statements	F-9
(2) Schedules required by Regulation S-X are filed as an exhibit to this report:	
I. Independent Registered Public Accounting Firm Report on Schedule	F-36
II. Schedule II — Valuation and Qualifying Accounts and Reserves	F-37

All other schedules have been omitted because they are not required, not applicable, or the required information is otherwise included.

(3) Exhibits

3.1	Certificate of Incorporation, as amended to date.(1)
3.2	By-laws, as amended to date.(2)
†4.3	1998 STAAR Surgical Company Stock Plan, adopted April 17, 1998.(3)
4.4	Form of Certificate for Common Stock, par value $0.01 per share.(4)
†4.5	Amended and Restated 2003 Omnibus Equity Incentive Plan and form of Option Grant and Stock Option Agreement.(5)
10.3	Indenture of Lease dated September 1, 1993, by and between the Company and FKT Associates and First through Third Additions Thereto.(6)
10.4	Second Amendment to Indenture of Lease dated September 21, 1998, between the Company and FKT Associates.(6)
10.5	Third Amendment to Indenture of Lease dated October 13, 2003, by and between the Company and FKT Associates.(7)
10.6	Fourth Amendment to Indenture of Lease dated September 30, 2006, by and between the Company and FKT Associates.(1)
10.7	Indenture of Lease dated October 20, 1983, between the Company and Dale E. Turner and Francis R. Turner and First through Fifth Additions Thereto.(8)
10.8	Sixth Lease Addition to Indenture of Lease dated October 13, 2003, by and between the Company and Turner Trust UTD Dale E. Turner March 28, 1984.(7)

10.9	Seventh Lease Addition to Indenture of Lease dated September 30, 2006, by and between the Company and Turner Trust UTD Dale E. Turner March 28, 1984.(1)
10.10	Amendment No. 1 to Standard Industrial/Commercial Multi-Tenant Lease dated January 3, 2003, by and between the Company and California Rosen LLC.(7)
10.11	Lease Agreement dated July 12, 1994, between STAAR Surgical AG and Calderari and Schwab AG/SA.(9)
10.12	Supplement #1 dated July 10, 1995, to the Lease Agreement of July 12, 1994, between STAAR Surgical AG and Calderari and Schwab AG/SA.(9)
10.13	Supplement #2 dated August 2, 1999, to the Lease Agreement of July 12, 1994, between STAAR Surgical AG and Calderari and Schwab AG/SA.(9)
10.20	Patent License Agreement, dated January 1, 1996, with Eye Microsurgery Intersectoral Research and Technology Complex.(10)
†10.42	Form of Indemnification Agreement between the Company and certain officers and directors.(9)
10.59	Standard Industrial/Commercial Multi Tenant Lease — Gross dated October 6, 2005, entered into between the Company and Z & M LLC.(11)
10.64	Warrant Agreement between STAAR Surgical Company and Broadwood Partners, L.P., dated March 21, 2007.(12)
†10.66	Executive Employment Agreement by and between the Company and Barry G. Caldwell, dated as of November 27, 2007.(13)
10.69	Warrant Agreement between STAAR Surgical Company and Broadwood Partners, L.P., dated December 14, 2007.(14)

†10.70	Amended and Restated Executive Employment Agreement by and between the Company and Barry G. Caldwell, dated December 31, 2008.(15)
†10.76	Employment Agreement effective November 22, 2002 by and between the Company and Deborah Andrews.(16)
†10.77	Letter of the Company dated April 11, 2007 to Deborah Andrews, Vice President and Chief Financial Officer, regarding compensation.(16)
10.80	Credit Agreement between STAAR Japan Inc. and Mizuho Bank Inc., dated October 31, 2007.(17)
10.81	Amended Credit Agreement between STAAR Japan Inc. and Mizuho Bank Ltd., dated June 30, 2009.(17)
10.82	Basic Agreement on Unsterilized Intraocular Lens Sales Transactions between Canon Staar Co., Inc. and Nidek Co., Ltd., dated May 23, 2005.(18)
10.83	Basic Agreement on Injector Product Sales Transactions between Canon Staar Co., Inc. and Nidek Co., Ltd., dated May 23, 2005.(18)
10.84	Memorandum of Understanding Concerning Basic Agreements for Purchase and Sale between STAAR Japan Inc. and Nidek Co., Ltd., dated December 25, 2008.(18)
10.85	Acrylic Preset supply Warranty Agreement between STAAR Japan Inc. and Nidek Co., Ltd., dated December 25, 2008.(18)
10.86	Framework Agreement for Loans between Credit Suisse and STAAR Surgical AG, dated August 12, 2010. (19)
†10.88	Form of Executive Severance Agreement.(20)
†10.89	Form of Executive Change In Control Agreement.(20)
10.90	Standard Industrial/Commercial Single – Tenant Lease – Net dated August 17 , 2012, by and between the Company and Pacific Equity Partners, LLC.(21)
†10.91	Letter of the Company dated March 27, 2012 to Samuel Gesten, Vice President and General Counsel, regarding compensation.*
†10.92	Letter of the Company dated August 10, 2012 to James Francese, Vice President, Global Marketing, regarding compensation.*
10.93	Amended Credit Agreement between STAAR Japan Inc. and Mizuho Bank Ltd., dated December 28, 2012.*
†10.94	Amendment No. 2 to Amended and Restated Executive Employment Agreement by and between the Company and Barry G. Caldwell, dated December 7, 2012.*
†10.95	Letter of the Company dated May 8, 2007 to Robin S. Hughes, Vice President of Marketing, regarding compensation.*
14.1	Code of Business Conduct and Ethics.(9)
21.1	List of Significant Subsidiaries.*
23.1	Consent of BDO USA, LLP.*
31.1	Certification Pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934, Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.*
31.2	Certification Pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934, Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.*
32.1	Certification Pursuant to 18 U.S.C. Section 1350, Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.*

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*Filed herewith

†Management contract or compensatory plan or arrangement

#All schedules and or exhibits have been omitted. Any omitted schedule or exhibit will be furnished supplementally to the Securities and Exchange Commission upon request.

(1)

Incorporated by reference to the Company's Annual Report on Form 10-K, for the year ended December 28, 2007, as filed on March 12, 2008.

(2) Incorporated by reference from the Company's Current Report on Form 8-K, as filed on May 23, 2006.

(3) Incorporated by reference to the Company's Proxy Statement for its Annual Meeting of Stockholders held on May 29, 1998, filed on May 1, 1998.

(4) Incorporated by reference to Exhibit 4.1 to Amendment No. 1 to the Company's Registration Statement on Form 8-A/A, as filed on April 18, 2003.

(5) Incorporated by reference to the Company's Proxy Statement for its Annual Meeting of Stockholders held on May 19, 2010, filed on April 9, 2010.

(6) Incorporated by reference to the Company's Annual Report on form 10-K for the year ended December 29, 2000, as filed on March 9, 2001.
(7) Incorporated by reference to the Company's Annual Report on Form 10-K, for the year ended January 2, 2004, as filed on March 17, 2004.
(8) Incorporated by reference from the Company's Annual Report on Form 10-K, for the year ended January 2, 1998, as filed on April 1, 1998.
(9) Incorporated by reference from the Company's Quarterly Report on Form 10-Q, for the period ended June 29, 2012, as filed on August 8,2012.
(10) Incorporated by reference to the Company's Annual Report on form 10-K for the year ended January 3, 1997, as filed on April 2, 1997.
(11) Incorporated by reference to the Company's Annual Report on form 10-K for the year ended December 29, 2000, as filed on March 28, 2002.
(11) Incorporated by reference to the Company's Quarterly Report on Form 10-Q for the period ended September 30, 2005, as filed on November 9, 2005.
(12) Incorporated by reference to the Company's Current Report on form 8-K filed on March 21, 2007.
(13) Incorporated by reference to the Company's Current Report on Form 8-K filed on December 4, 2007.
(14) Incorporated by reference to the Company's Current Report on form 8-K filed on December 17, 2007.
(15) Incorporated by reference to the Company's Current Report on Form 8-K filed on January 8, 2009.
(16) Incorporated by reference to the Company's Current Report on Form 8-K filed on October 1, 2009.
(17) Incorporated by reference to the Company's Quarterly Report on Form 10-Q for the period ended October 2, 2009, as filed on November 12, 2009.
(18) Incorporated by reference to the Company's Annual Report on Form 10-K for the year ended January 1, 2010.
(19) Incorporated by reference to the Company's Quarterly Report on Form 10-Q for the period ended October 1, 2010, as filed on November 10, 2010.
(20) Incorporated by reference to the Company's Quarterly Report on Form 10-Q for the period ended September 30, 2011, as filed on November 2, 2011.
(21) Incorporated by reference to the Company's Current Report on Form 8-K files on August 23, 2012.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

STAAR SURGICAL COMPANY

Date: March 12, 2013 By: /s/ Barry G. Caldwell
Barry G. Caldwell
President and Chief Executive Officer
(principal executive officer)

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

Name	Title	Date
/s/ Barry G. Caldwell Barry G. Caldwell	President, Chief Executive Officer and Director (principal executive officer)	March 12, 2013
/s/ Deborah Andrews Deborah Andrews	Vice President, Chief Financial Officer (principal accounting and financial officer)	March 12, 2013
/s/ Don Bailey Don Bailey	Chairman of the Board, Director	March 12, 2013
/s/ Donald Duffy Donald Duffy	Director	March 12, 2013
/s/ John C. Moore John C. Moore	Director	March 12, 2013
/s/ Richard A. Meier Richard A. Meier	Director	March 12, 2013
/s/ Mark B. Logan Mark B. Logan	Director	March 12, 2013
/s/ Charles Slacik Charles Slacik	Director	March 12, 2013

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STAAR SURGICAL COMPANY AND SUBSIDIARIES

CONSOLIDATED FINANCIAL STATEMENTS

Years Ended December 28, 2012, December 30, 2011, and December 31, 2010

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STAAR SURGICAL COMPANY AND SUBSIDIARIES

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Stockholders

STAAR Surgical Company

Monrovia, CA

We have audited the accompanying consolidated balance sheets of STAAR Surgical Company and Subsidiaries (the "Company") as of December 28, 2012 and December 30, 2011, and the related consolidated statements of operations, comprehensive income (loss), stockholders' equity, and cash flows for each of the three years in the period ended December 28, 2012. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of STAAR Surgical Company and Subsidiaries as of December 28, 2012 and December 30, 2011, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 28, 2012, in conformity with accounting principles generally accepted in the United States of America.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), STAAR Surgical Company and Subsidiaries' internal control over financial reporting as of December 28, 2012, based on criteria established in *Internal Control – Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) and our report dated March 12, 2013 expressed an unqualified opinion thereon.

/s/ BDO USA, LLP

Los Angeles, California

March 12, 2013

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STAAR SURGICAL COMPANY AND SUBSIDIARIES

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Stockholders

STAAR Surgical Company

Monrovia, CA

We have audited STAAR Surgical Company and Subsidiaries' internal control over financial reporting as of December 28, 2012, based on criteria established in *Internal Control – Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). STAAR Surgical Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Item 9A, Management's Annual Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audit also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, STAAR Surgical Company and Subsidiaries maintained, in all material respects, effective internal control over financial reporting as of December 28, 2012, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of STAAR Surgical Company and Subsidiaries as of December 28, 2012 and December 30, 2011, and the related consolidated statements of operations, comprehensive income (loss), stockholders' equity, and cash flows for each of the three years in the period ended December 28, 2012 and our report dated March 12, 2013 expressed an unqualified opinion thereon.

/s/ BDO USA, LLP

Los Angeles, California

March 12, 2013

STAAR SURGICAL COMPANY AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

December 28, 2012 and December 30, 2011

	2012	2011
	(In thousands, except par value amounts)	
ASSETS		
Current assets:		
Cash and cash equivalents	$21,675	$16,582
Restricted cash	—	129
Accounts receivable trade, net	8,543	9,089
Inventories, net	11,673	10,933
Prepaids, deposits and other current assets	2,183	1,921
Total current assets	44,074	38,654
Property, plant and equipment, net	5,439	4,222
Intangible assets, net	2,142	2,989
Goodwill	1,786	1,786
Deferred income taxes	187	152
Other assets	1,131	1,203
Total assets	$54,759	$49,006
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Line of credit	$5,850	$2,580
Accounts payable	5,129	4,261
Deferred income taxes	439	472
Obligations under capital leases	829	597
Other current liabilities	5,702	6,106
Total current liabilities	17,949	14,016
Obligations under capital leases	488	1,124
Deferred income taxes	885	708
Pension liability	2,988	2,760
Asset retirement obligations	707	577
Other long-term liabilities	—	363
Total liabilities	23,017	19,548
Commitments, contingencies and subsequent events (Note 14)		
Stockholders' equity:		
Common stock, $0.01 par value; 60,000 shares authorized: 36,423 and 36,041 shares issued and outstanding at December 28, 2012 and December 30, 2011, respectively	364	361
Additional paid-in capital	162,251	157,382
Accumulated other comprehensive income	1,580	2,405

Accumulated deficit	(132,453)	(130,690)
Total stockholders' equity	31,742	29,458
Total liabilities and stockholders' equity	$54,759	$49,006

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

STAAR SURGICAL COMPANY AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF OPERATIONS

Years Ended December 28, 2012, December 30, 2011, and December 31, 2010

	2012	2011	2010
	(In thousands, except per share amounts)		
Net sales	$63,783	$62,765	$54,958
Cost of sales	19,492	20,396	19,882
Gross profit	44,291	42,369	35,076
Selling, general and administrative expenses:			
General and administrative	15,150	14,932	14,778
Marketing and selling	21,281	17,726	17,176
Research and development	6,444	5,868	5,724
Other general and administrative expenses	2,636	1,060	—
Operating income (loss)	(1,220)	2,783	(2,602)
Other income (expense):			
Interest income	59	32	43
Interest expense	(291)	(523)	(896)
Gain (loss) on foreign currency transactions	111	86	(87)
Loss on early extinguishment of note payable	—	—	(267)
Other income, net	822	326	128
Other income (expense), net	701	(79)	(1,079)
Income (loss) before provision for income taxes	(519)	2,704	(3,681)
Provision for income taxes	1,244	1,356	432
Income (loss) from continuing operations	(1,763)	1,348	(4,113)
Income from discontinued operations, net of income taxes	—	—	4,166
Net income (loss)	$(1,763)	$1,348	$53

Income (loss) per share from cont