STAAR SURGICAL CO
Form 10-K
March 13, 2015

**UNITED STATES SECURITIES AND EXCHANGE COMMISSION**

**Washington, D.C. 20549**

**Form 10-K**

**(Mark One)**

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

**For the fiscal year ended January 2, 2015**
**or**
¨ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

**For the Transition period from to**

**Commission file number: 0-11634**

**STAAR SURGICAL COMPANY**

*(Exact name of registrant as specified in its charter)*

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

**1911 Walker Avenue**

**Monrovia, California 91016**

*(Address of principal executive offices)*

**(626) 303-7902**

(Registrant's telephone number, including area code)

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

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

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

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

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

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

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. Yes ¨ No þ

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

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

(Do not check if a smaller reporting company)

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant as of July 4, 2014, the last business day of the registrant's most recently completed second fiscal quarter, was approximately $542,806,000 based on the closing price per share of $14.15 of the registrant's Common Stock on that date.

The number of shares outstanding of the registrant's Common Stock as of March 11, 2015 was 38,797,569.

**DOCUMENTS INCORPORATED BY REFERENCE**

Portions of the registrant's definitive proxy statement relating to its 2015 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 and delivery systems used to deliver the lenses into 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 treats 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®, CentraFLOW®, AquaPORT®, 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 14. 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 85% of our total sales in fiscal year 2014, primarily due to the pacing of product approvals and commercialization that tend to occur first outside the U.S. STAAR sells its products in more than 60 countries, with direct distribution in the United States, Canada, Japan and Spain, and independent distribution in the remainder of the world.

STAAR maintains operational and administrative facilities in the United States, Switzerland and Japan. In June 2014 STAAR completed a project to consolidate substantially all of its manufacturing in 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. We also manufacture the Visian implantable Collamer lenses (ICLs) and preloaded IOL injectors. STAAR 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 and distribution facility in Nidau, Switzerland under its wholly owned subsidiary, STAAR Surgical AG. The Nidau facility also maintains manufacturing capabilities for STAAR's ICL products and the AquaFlow Device.

- *Japan*. STAAR operates administrative 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 distribution facility is located in Ichikawa City. STAAR final packages its silicone preloaded IOL injectors at the Ichikawa City facility.

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 also exposes us to the risk of unexpected costs and possible supply interruptions. See "*Item 1A. Risk Factors —Risks Related to Our Business —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"; and "—We may not realize the expected benefits of our manufacturing consolidation 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. The eye has an anterior segment and a posterior segment that are separated by the natural crystalline lens.

The anterior segment consists of the cornea, the iris and ciliary body and the trabecular meshwork. It is filled with a watery fluid called aqueous humor and is divided, by the iris, into an anterior chamber and a posterior chamber. 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 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 posterior segment of the eye that is behind the natural lens is filled with a jelly-like material called the vitreous humor. 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 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 due to an irregular curvature of the cornea or defects in the natural lens. In an eye with astigmatism, light fails to come to a single focus on the retina. Instead, two or more focus points occur that results in blurred vision. 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 16 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 product line 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, which also corrects for astigmatism) 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 500,000 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. By simplifying the procedure and increasing patient comfort, the CentraFLOW technology makes the 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 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, China, Korea, Japan, India and certain countries in the Middle East. STAAR submitted its application for U.S. approval of the TICL to the FDA in 2006 which is currently under review (see *“Regulatory Matters – Regulatory Requirements in the United States – Status of Toric ICL Submission”*).

The Hyperopic ICL, which treats far-sightedness, is approved for use in countries that require the European Union CE Mark and in 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 totaling hundreds of different types of 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 ship approximately 76% in less than one week from receipt of an order at our manufacturing facility.

Sales of ICLs (including TICLs) accounted for approximately 59% of our total sales in fiscal 2014, 61% of our total sales in fiscal 2013, and 55% of our total sales in fiscal 2012.

*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 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 offers 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) 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 has a high water content, 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 that use optical designs that produce a clearer image than traditional spherical lenses, especially in low light. For example, the STAAR nanoFLEX IOL is 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 and Europe, 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. In China, we sell a "Preloaded Injector" with a silicone 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 us. Our 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 32% of our total sales in fiscal 2014, 33% of our total sales in fiscal 2013, and 41% of our total sales in fiscal 2012.

**Other Surgical Products**

We also sell other related instruments and devices that we manufacture or that are manufactured by others, but these products have relatively lower overall gross profit margins. Also, we sell injector parts to our lens supplier for their preloaded acrylic IOL that they sell under their own brand. Sales of other surgical products accounted for approximately 9% of our total sales in fiscal 2014, 5% of our total sales in fiscal 2013, and 4 % of our total sales in fiscal 2012.

**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.

**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 January 2, 2015, we owned approximately 67 United States and foreign patents and had approximately 21 patent applications pending. In addition, as of January 2, 2015, our Japanese subsidiary owned approximately 50 Japanese and foreign patents and had approximately 2 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 important to the safety and effectiveness of its ICLs, and that we believe would be necessary or desirable for any competing posterior chamber phakic IOL. Some of these patents expire by the end of 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 by the end of 2016, with the last blocking patent expiring in 2017. Over the past two years, we have 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 patents with up to five years of life remaining.

In addition to patents, we possess trade secrets and know-how regarding the design and production of the collamer material and the manufacture of ICLs all of which we perform internally. We believe it would require extensive time and effort for a competitor to duplicate these processes to develop a product with comparable capabilities to the ICL product line.

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.

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, although the third quarter may be lower due to the summer vacation effect in Europe.

**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, social media sites, 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, accounted for more than 10% of our consolidated net sales during fiscal 2013 and 2012, although this decreased to approximately 9% during fiscal 2014. Net sales to WooJeon during each of the last three fiscal years were as follows:

Net Sales to WooJeon

| Fiscal Year | Net Sales ($, in thousands) | Net Sales as Percentage of Consolidated Net Sales |
|---|---|---|
| 2014 | $ 6,563 | 8.8 % |
| 2013 | $ 7,743 | 10.7 % |
| 2012 | $ 6,713 | 10.5 % |

**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 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. In the fourth quarter of 2014, we experienced a backlog for ICLs and TICLs primarily due to manufacturing challenges in our Monrovia facility. Also, we implemented a voluntary hold on over 2,000 ICLs from shipment at the end of the quarter. The impact of these manufacturing challenges to our revenue in the fourth quarter of 2014 was approximately $1.0 million. We continue to address the issues and expect to reduce the backlog to customary levels by the end of the first quarter 2015 or the end of the second quarter. If we cannot resolve our manufacturing challenges in the first quarter of 2015, our financial results may be adversely impacted.

**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 (formerly Advanced Medical Optics or AMO), and Valeant (formerly Bausch & Lomb or 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. Start-up competitors from a low cost manufacturing geography are beginning to appear in the market with a low cost alternative to the ICL, though we do not believe they are having a material impact on our sales at this time.

As with the refractive market, the global cataract market is highly concentrated, with the top three competitors (Novartis, Abbott and Valeant) combined accounting for approximately 70% of total market revenue, according to internal estimates and a 2014 report by Market Scope, LLC, a publisher of ophthalmic industry analysis.

**Regulatory Matters**

Nearly all countries where we sell our products have regulations requiring premarket clearance or approval 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 clearance or approval 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 clearance or approval to distribute medical products is costly and time-consuming in virtually all of the major markets where we sell medical devices.

We cannot give any assurance that any new medical devices we develop will be cleared or approved in a country where we propose to sell our medical devices or, if approved, whether such approvals will be granted in a timely or cost-effective manner. We also cannot give any assurance that if our medical devices are approved for sale in a country action will not be taken by the responsible regulatory authorities in the country with respect to our medical devices that might affect our ability to maintain the required approvals in the country or to continue to sell our medical devices in the country. The regulatory requirements in our most important current markets, the U.S., Europe and Japan, and in China and Korea 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 regulate, among other things, the design, development, manufacturing, preclinical and clinical testing, labeling, product safety, marketing, sales, distribution, pre-market clearance and approval, recordkeeping, reporting, advertising, promotion, post-market surveillance, and import and export of medical devices.

Most of our products are medical devices intended for human use within the meaning of the Act and, therefore, are subject to FDA regulation.

Each medical device we seek to commercially distribute in the United States must first receive clearance to market under a notification submitted pursuant to Section 510(k) of the Act, known as the 510(k) premarket notification, or

pre-market approval (PMA) from the FDA, unless specifically exempted by the agency. The FDA classifies all medical devices into one of three classes. The FDA establishes procedures for compliance based upon the device's classification 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). Devices deemed to pose lower risk are categorized as either Class I or II, which require the manufacturer to submit to the FDA a 510(k) pre-market notification requesting clearance of the device for commercial distribution in the United States. Some low risk devices are exempt from this requirement. Class III devices are deemed by the FDA to pose the greatest risk and are the most extensively regulated. These devices include life-supporting, life sustaining, or implantable devices, or devices deemed not substantially equivalent to a previously 510(k) cleared device. 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.* Our lens injector systems are Class I devices subject to the 510(k) pre-market review and clearance process. A medical device that is substantially equivalent to either a previously-cleared medical device or a device that was in commercial distribution before May 28, 1976 for which the FDA has not yet called for the submission of a PMA, or is a device that has been reclassified from Class III to either Class II or I may be eligible for the FDA's 510(k) pre-market notification 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. The review period and FDA determination as to substantial equivalence generally takes from three to twelve months from the date the application is submitted and filed. However, the process may take significantly longer, and clearance is never assured. Although many 510(k) pre-market notifications are cleared without clinical data, in some cases, the FDA requires significant clinical data to support substantial equivalence. In reviewing a pre-market notification, the FDA may request additional information including clinical data, which may significantly prolong the review process.

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 pre-market approval. The FDA requires each manufacturer to make its own initial determination as to whether a change meets this threshold. 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 a PMA is obtained. We have modified aspects of some of our devices since receiving 510(k) clearance, and have determined that no new clearance or approval was required. If the FDA requires us to seek 510(k) clearance or pre-market 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.

*Premarket Approval*. Our IOLs, ICLs, and AquaFlow Devices are Class III devices subject to the PMA approval process. 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 for its intended use. A PMA must be supported by, among other things, extensive technical, pre-clinical, clinical testing, manufacturing and labeling data to demonstrate to the FDA's satisfaction the safety and effectiveness of the device.

After a PMA application is submitted and filed, the FDA begins an in-depth review of the submitted information, which typically takes between one and three years, but may take significantly longer. During the review period, the FDA may request additional information or clarification of information already provided. 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. In addition, the FDA will conduct a pre-approval inspection of the manufacturing facility to ensure compliance with Quality System Regulation (QSR) which imposes elaborate design development, testing, control, documentation and other quality assurance procedures in the design and manufacturing process. The FDA may approve a PMA application with post-approval conditions intended to ensure the safety and effectiveness of the device including, among other things, restrictions on labeling, promotion, sale and distribution and collection of long-term follow-up from patients in the clinical study that supported approval. Failure to comply with the conditions of approval can result in materially adverse enforcement action, including the loss or withdrawal of the approval.

If a manufacturer plans to make significant modifications to the manufacturing process, labeling, or design of an approved PMA device, 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 certain changes 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.

*Clinical or Market Trials.* A clinical trial is typically required to support a PMA application and is sometimes required for a 510(k) pre-market notification. Clinical trials generally require submission of an application for an Investigational Device Exemption (IDE) to the FDA. The IDE application must be supported by appropriate data, such as animal and laboratory testing results, showing that it is safe to test the device in humans and that the investigational protocol is scientifically sound. The IDE application must be approved in advance by the FDA for a specified number of patients, unless the product is deemed a non-significant risk device and eligible for more abbreviated IDE requirements. Clinical trials for a significant risk device may begin once the IDE application is approved by the FDA as well as the appropriate institutional review boards (IRBs) at the clinical or market trial sites, and the informed consent of the patients participating in the clinical trial is obtained. After a trial begins, the FDA may place it on hold or terminate it if, among other reasons, it concludes that the clinical subjects are exposed to an unacceptable health risk. Any trials we conduct in the U.S. must be conducted in accordance with FDA regulations as well as other federal regulations and state laws concerning human subject protection and privacy. Moreover, the results of a clinical trial may not be sufficient to obtain clearance or approval of the product.

*Oversight of compliance with quality, medical device reporting and other regulations.* Both before and after we receive pre-market clearance or approval and release a product commercially, we have ongoing responsibilities under FDA regulations. The FDA 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 for medical devices known as the QSR, 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.

The FDA's Bioresearch Monitoring Program (BIMO), 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.

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 risk or substantial harm to 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 issue warning letters or untitled letters, refuse our request for 510(k) clearance or PMA approval, revoke existing 510(k) clearances or PMA approvals previously granted, 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.

For example, in 2007 we received a warning letter following a BIMO inspection that identified negative inspectional observations. Prior to the inspection and the warning letter, we submitted a PMA supplement for the TICL to the FDA on April 28, 2006, which the agency designated as a panel-track supplement. In August 2007, following negative inspectional observations and the warning letter the FDA Office of Device Evaluation placed an integrity hold on our TICL application. Over a two-year period we 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 us that as a result of our corrective actions the FDA had removed the integrity hold on the application for approval of the TICL, and would resume its consideration of the application. On February 3, 2010, we received a letter of deficiency from the FDA outlining additional questions. After several communications with the FDA, on November 29, 2011, we received a letter of deficiency from the FDA further questioning the clinical data. After further interactions with the FDA throughout 2012, on November 15, 2012, we submitted (1) clinical data showing no statistical difference in the clinical outcomes with or without 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. On March 14, 2014 an FDA Ophthalmic Devices Panel of the Medical Devices Advisory Committee that assessed our PMA Supplement submission seeking approval of the TICL, voted favorably in response to the three questions posed to it by the FDA's Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices regarding the TICL's safety and effectiveness as well as whether the TICL's benefits outweigh its risks.

On May 27, 2014, we received a warning letter from the FDA (the "2014 Warning Letter") citing alleged violations of current good manufacturing practice ("cGMP") regulations that were identified by the FDA during an inspection of the Company's manufacturing facility in Monrovia, California between February 10, 2014 and March 21, 2014. To summarize, the 2014 Warning Letter observations require remedial action in four general areas: design control documentation; validation of software for an on-line calculator; data collection and trending of ICL vault complaints; and shelf life data on the ICL product. The 2014 Warning Letter provides that, until the Company addresses the

deficiencies to the FDA's satisfaction, the FDA will not approve premarket applications ("PMAs") for the Company's Class III devices where the applications are reasonably related to the cGMP violations cited in the 2014 Warning Letter.

Beginning on November 14, 2014 and continuing through February 4, 2015, the FDA inspected our Monrovia facility. On February 4, 2015, at the conclusion of the inspection, the FDA issued the 2015 FDA-483 with ten inspectional observations ("2015 FDA-483"). The observations focus primarily on the need for adherence to and improved procedures, processes and documentation relating to design change, design transfer into specifications and production, verification and validation associated with device design and production, improvement in good documentation practices, and broader environmental monitoring. STAAR responded to the FDA-483 and is concurrently continuing to develop and implement its corrective action plans relating to the 2014 Warning Letter and the 2015 FDA-483. While the PMA supplement remains pending, we cannot predict when, or if, the FDA will grant approval of the TICL for use in the United States.

Our ability to continue our U.S. business depends on the continuous improvement of our quality systems and our ability to demonstrate compliance with FDA regulations. Accordingly, our management expects to continue to devote significant resources and attention to those efforts for the foreseeable future.

***Healthcare Fraud and Abuse Laws and Regulations***

Even though we do not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third-party payers, certain federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights are applicable to our business. We are subject to healthcare fraud and abuse and patient privacy regulation by both the federal government and the states in which we conduct our business. The regulations that may affect our ability to operate include, without limitation:

- the federal Anti-Kickback Statute, which prohibits, among other things, any person from knowingly and willfully offering, soliciting, receiving or providing remuneration, directly or indirectly, to induce either the referral of an individual, for an item or service or the purchasing or ordering of a good or service, for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs;

- the federal False Claims Act, which prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, false claims, or knowingly using false statements, to obtain payment from the federal government, and which may apply to entities that provide coding and billing advice to customers;

- federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;

- the federal physician sunshine requirements under the Health Care Reform Law, which requires manufacturers of drugs, devices, biologics, and medical supplies to report annually to the Centers for Medicare & Medicaid Services information related to payments and other transfers of value relating to certain drugs, devices, biologics, and medical supplies to physicians, other healthcare providers, and teaching hospitals, and ownership and investment interests held by physicians and other healthcare providers and their immediate family members;

- the federal Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act, which governs the conduct of certain electronic healthcare transactions and protects the security and privacy of protected health information; and

- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payer, including commercial insurers; state laws that require device companies to comply with the industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that require device manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state laws governing the privacy and security of health information in certain circumstances, which may differ from each other and may not have the same effect, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. In addition, recent health care reform legislation has strengthened these laws. For example, the recently enacted Health Care Reform Law, among other things, amends the intent requirement of the Federal Anti-Kickback Statute and criminal healthcare fraud statutes. A person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it. In addition, the Affordable Care Act provides that the government may assert that a claim including items or services resulting from a violation of the Federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act.

Achieving and sustaining compliance with these laws may prove costly. In addition, any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, the exclusion from participation in federal and state healthcare programs, imprisonment, or the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business, our reputation and our financial results.

***Regulatory Requirements outside the United States.***

*CE Marking*. In the European Economic Area (EEA), which is comprised of the 28 Member States of the European Union plus Norway, Iceland, and Liechtenstein, medical devices must comply with the essential requirements of the EU Medical Devices Directive (Council Directive 93/42/EEC). Compliance with the essential requirements of the EU Medical Device Directive is a prerequisite to be able to affix a *Conformité Européenne* Mark (CE Mark), without which medical devices cannot be marketed or sold in the EEA. To demonstrate compliance with the essential requirements, medical device manufacturers must undergo a conformity assessment procedure, which varies according to the type of medical device and its classification.

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 review 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. 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.

We have affixed the CE Mark to all of our principal products including ICL and TICL products, IOLs, injector systems and our AquaFlow Device.

*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. If the PMDA 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, they could take a variety of regulatory or legal actions, similar to the FDA, which could have a material and negative impact on the Company.

*Medical Device Regulation in China and Korea.* Sales of our products in China and Korea, as in other countries, are also subject to regulatory requirements. In China, medical devices such as our ICLs and IOLs require testing by a government recognized laboratory qualified as a medical device testing center in accordance to Chinese standards. Results from the testing center, together with registration documents are submitted to the Center for Medical Device Evaluation (CMDE) of the Chinese FDA (CFDA) for technical evaluation and if accepted, then approval and registration by CFDA. In China, we obtain registration of our products from CFDA ourselves. In Korea, medical devices such as our ICLs and IOLs require registration and approval from the Korean Ministry of Food and Drug Safety (MFDS) prior to commercialization. Typically, the MFDA requires similar documentation as required to obtain a CE Mark. Our distributor in Korea is contractually required to obtain, with our assistance, the necessary health registrations, governmental approvals or clearances to import, market and sell our products. We provide our distributor with information and data to obtain appropriate registrations and approvals, and the distributor obtains such registrations. If the CFDA or MFDS 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, they could take a variety of regulatory or legal actions in their respective countries, similar to the FDA, which could have a material and negative impact on the Company.

***Third Party Coverage and Reimbursement***

Health care providers generally rely on third-party payers, including governmental payers such as Medicare and Medicaid, private insurance plans and workers' compensation plans, to cover and reimburse the cost of medical devices and related services. These third-party payers may deny coverage or reimbursement for a medical device if they determine that the product or procedure using the product was not medically appropriate or necessary and are increasingly challenging the price of medical devices and services.

Our ICL products generally are not covered by third-party payers, and patients incur out-of-pocket costs for these products and related procedures using our products. Our IOL products used in cataract procedures generally are covered by third-party payers, including Medicare, in whole or in part depending upon a variety of factors, including the specific product used and geographic location where the procedure using the covered product is performed. The market for some of our IOL products therefore is influenced by third-party payers' policies.

In the United States, the Centers for Medicare & Medicaid Services, the agency responsible for administering the Medicare program, or CMS, sets coverage and reimbursement policies for the Medicare program. CMS may modify its coverage and reimbursement policies related to IOLs, including our IOLs, as well as cataract procedures using IOLs, at any time. Since the enactment of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, the Health Care Reform Law, there have been an increasing number of legislative initiatives in the United States to contain health care coverage and reimbursement by governmental and other payers. These new laws, as well as future laws that may be enacted, may result in additional reductions in Medicare and other health care funding, which could have a material adverse effect on our customers and thus, our financial operations.

In international markets, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted cost containment initiatives similar to those in the United States. For example, price reductions have been mandated in several European countries, including Germany, Italy and Spain. There can be no assurance that third-party coverage and reimbursement will be available or adequate, or that such policies or any future legislation or regulation will not adversely affect the demand for our IOLs or our ability to sell these products at the prices they want.

**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 active internal research and development programs, which also include clinical activities and regulatory affairs and are

comprised of approximately 20 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 2013 we began introducing the nanoFLEX Toric Collamer IOL in selected countries that accept the CE Mark. During 2012, we introduced the KS-SP Preloaded Hydrophobic Acrylic Injector System in Japan and limited markets in Europe. During 2011, we 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 2015, we intend 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; and

- Development of presbyopia-correcting IOLs and ICLs.

Research and development expenses were approximately $12.4 million, $6.7 million, and $6.4 million for our 2014, 2013, and 2012 fiscal years, respectively. We expect to invest approximately 12% of sales for research and development in 2015. During 2014, research and development expenses increased $5.7 million including $2.2 million for new product development and increased headcount, $1.8 million for FDA remediation activities, and $1.5 million for the FDA Advisory Panel meeting related to our PMA Supplement seeking U.S. approval for our Toric ICL. The Company expects to continue its FDA remediation activities through 2016 and expects to spend approximately $4 million for these activities in 2015.

**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.

**Employees**

As of March 13, 2015, we employed approximately 300 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.

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

***three-piece IOL*** – a three-piece IOL has a central, disk-shaped optic and two spring-like 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 have a history of losses that could continue in the future.***

During 2011, we achieved net income after reporting losses for more than ten years. However, in two of the past three years we reported losses. Our 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 $140.4 million as of January 2, 2015. Our ability to fund our capital requirements out of our available cash and cash generated from our operations depends on a number of factors, including our ability to continue growing our existing operations. If we cannot continue to generate positive cash flow from operations, we will have to reduce our costs and try to raise working capital from other sources. These measures could materially and adversely affect our ability to execute our operations and expand our business.

***We compete with much larger companies.***

Our competitors, including Novartis (formerly Alcon), Abbott (formerly Advanced Medical Optics, or AMO) and Valeant (formerly 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 FDA's Center for Devices and Radiological Health regularly inspects our facilities to determine whether we are in compliance with the FDA Quality System Regulation, which governs such things as manufacturing practices, validation, testing, quality control, product labeling and complaint handling, and in compliance with FDA Medical Device Reporting regulations for certain adverse events and device malfunctions, and other FDA regulations. The FDA also regularly inspects for compliance with regulations governing advertising and promotional activities as well as clinical investigations.

While we believe that we are substantially in compliance with the FDA's Quality System Regulations, quality system deficiencies observed at certain of our facilities during prior inspections have led to FDA Warning Letters and delays in product approvals until we resolved agency concerns. For example, in 2007, we received a Warning Letter identifying deficiencies in clinical study procedures, practices and documentation related to the Toric ICL, or TICL. As a result, the FDA placed an integrity hold on the TICL PMA supplement application in August 2007, which was lifted in July 2009

On May 27, 2014, we received the 2014 Warning Letter from the FDA citing alleged violations of current good manufacturing practice ("cGMP") regulations that were identified by the FDA during an inspection of the Company's manufacturing facility in Monrovia, California between February 10, 2014 and March 21, 2014. To summarize, the 2014 Warning Letter observations require remedial action in four general areas: design control documentation; validation of software for an on-line calculator; data collection and trending of ICL vault complaints; and shelf life

data on the ICL product." The 2014 Warning Letter provides that, until the Company addresses the deficiencies to the FDA's satisfaction, the FDA will not approve PMAs for the Company's Class III devices where the applications are reasonably related to the cGMP violations cited in the Warning Letter.

Beginning on November 14, 2014 and continuing through February 4, 2015, the FDA inspected our Monrovia facility. On February 4, 2015, at the conclusion of the inspection, the FDA issued a Form FDA-483 with ten inspectional observations. The observations focus primarily on the need for adherence to and improved procedures, processes and documentation relating to design change, design transfer into specifications and production, verification and validation associated with device design and production, improvement in good documentation practices, and broader environmental monitoring.

We timely responded to the 2014 Warning Letter and the 2015 FDA-483 and are continuing to develop and implement our corrective action plans related to both of these issuances.

While the PMA supplement remains pending, we cannot predict when, or if, the FDA will grant approval of the TICL for use in the United States.

Our ability to continue our U.S. business depends on the continuous improvement of our quality systems and constant vigilance in our compliance with FDA regulations. Accordingly, our management expects to continue to devote significant resources and attention to those efforts for the foreseeable future. We cannot ensure that our 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 worldwide, which increases our costs and could prevent us from selling our products*" and "*—We are subject to federal and state regulatory investigations*."

***The 2014 Warning Letter and the 2015 FDA-483 may adversely impact our operations.***

As noted above, we received the 2014 Warning Letter and the 2015 FDA-483, have responded, and continue to develop and implement our corrective action plans relating to them. There can be no assurance that the FDA will be satisfied with the Company's response to the 2014 Warning Letter or the 2015 FDA-483. Unless and until STAAR is able to correct outstanding issues to the FDA's satisfaction, the FDA may withhold approval of new products such as the Toric ICL (TICL). In addition, the Company may be subject to additional regulatory action by the FDA, including fines, injunctions, warning letters, consent decrees, prosecution, civil money penalties, repairs, replacements, refunds, recalls or seizures of products, total or partial suspension of production, the FDA's refusal to grant future premarket approvals, withdrawals or suspensions of current products. Any such further action could, ultimately, be significant to our ongoing business and operations.

***FDA approval of the Visian Toric ICL, which could have a significant U.S. market, has been considerably delayed.***

An important part of our ICL product portfolio is the 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. We believe the TICL has a significant potential market in the U.S. and could accelerate growth of the overall refractive product line. We 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. On March 14, 2014 a FDA Ophthalmic Devices Panel of the Medical Devices Advisory Committee voted favorably in response to the three questions posed to it by the FDA's Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices (regarding the TICL's safety and effectiveness as well as whether the TICL's benefits outweigh its risks).

Between February 10, 2014 and March 21, 2014, the FDA inspected our manufacturing facility in Monrovia, California. On May 27, 2014, we received the 2014 Warning Letter from the FDA citing alleged violations of current good manufacturing practice ("cGMP") regulations that were identified by the FDA during the inspection. Between November 14, 2014 and February 4, 2015, the FDA again inspected our manufacturing facility in Monrovia, California. On February 4, 2015, at the completion of this inspection, the FDA issued the FDA-483 with ten inspectional observations. 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,*" "*—We are subject to federal and state regulatory investigations," and "FDA compliance issues have delayed approvals and we expect to devote significant resources to maintaining compliance in the future."*

While the PMA supplement remains pending, we cannot predict when, or if, the FDA will grant approval of the TICL for use in the United States.

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

The results of operations and the financial position of our Japanese subsidiary are reported in Japanese yen and then translated into U.S. dollars at the applicable exchange rates for inclusion in our consolidated financial statements, exposing us to translation risk. Year over year fluctuations in the exchange rate between the Japanese yen and the U.S. dollar had a $1.6 million impact on Japanese yen translated sales for the fiscal year ended January 2, 2015. In addition, we are exposed to transaction risk because some of our sales and expenses are incurred in a currency different from the U.S. dollar. Our most significant currency exposures are to the Japanese yen, the euro, and the Swiss Franc, and the exchange rates between these currencies and the U.S. dollar may fluctuate substantially. As more manufacturing has shifted from Japan to the U.S. there will be increased foreign currency exposure to the Japanese yen. 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. For example, sales in certain Asian and developing markets may result in lower margins and higher exposure to intellectual property infringement or counterfeits. 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 rely and depend on independent distributors in international markets***.

Except for the U.S., Canada, Japan, and Spain, we sell our 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 2014, sales to our independent distributor in Korea, our second largest market, declined by 15% compared to 2013, but in 2013 increased by 15% over 2012.

***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 our business is challenging. While we seek to integrate our foreign subsidiaries fully into our operations, direct supervision of every aspect of the subsidiaries' operations is impossible, and as a result we rely on the local managers and staff of these subsidiaries. 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. We periodically provide anti-corruption training to relevant employees and distributors. 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 growth declined globally in 2014, we believe that negative economic conditions have contributed to this decline. Economic stagnation, lack of consumer confidence or new recessions in any of our key markets, including but not limited to Korea, China, Japan, or Spain, could further slow ICL sales growth or, if severe, cause declines in sales. Because the ICL is our highest gross margin product, restricted growth or a decline in its sales could materially harm our 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 several refractive surgery markets in 2013 and 2014. In December 2013, the Consumer Affairs Agency of the Japanese government issued an official cautionary warning for individuals interested in LASIK eyesight correction procedures. We believe this affected the volume of refractive surgery in Japan in 2014. In Korea in June 2014, a regional television station reported that outcomes from LASIK surgery harmed patients and significantly lowered their quality of life. A similar program was later broadcast on a national television station in that country. 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. We believe this negative publicity decreased patient interest in Korea 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. 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. 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. The results of this study were presented in October 2014 and can be found on the FDA website. Some of the findings could amplify concerns about complications of laser refractive surgery. While these concerns could encourage patients and physicians to select the ICL as an alternative, they could also decrease patient interest in all refractive surgery, including ICL.

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

Since 2011 we have invested significant resources in manufacturing consolidation and a tax strategy initiative, and we have invested approximately $6.3 million dollars to complete the consolidation. The goal 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 could be affected by delays or cause supply interruptions, changes in tax laws could reduce or eliminate expected benefits of some of our tax strategies, tax authorities may challenge our tax strategy, or future profit margins could be affected by a variety of factors unrelated to our level of manufacturing efficiency. In June 2013, we completed transferring IOL manufacturing from Japan to our Monrovia, California facility. In June 2014, we completed transferring ICL manufacturing from Nidau to our Monrovia, California facility, while maintaining manufacturing capabilities in Nidau. Completion of remaining consolidation may result in disruption to our business and delays in our use of tax loss carry forwards, which would adversely affect our results. For example, we experienced lower manufacturing yields in Monrovia than typically experienced in Nidau in the fourth quarter of 2014.

***Our manufacturing consolidation exposes us to risk.***

We have described our manufacturing consolidation initiative and provided an update to our progress in the "*Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations—Overview—Other Highlights—Manufacturing Consolidation Project and Tax Strategy"* section of this Report. Transferring the manufacturing of medical devices is more expensive, time-consuming and riskier 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 we have placed a priority on maintaining the continuity and quality of our product supply, including increasing our 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, our manufacturing consolidation results in our no longer having 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. We and our third-party manufacturers and suppliers are required to comply with the FDA's QSR, which covers the methods and documentation of the design, testing production, control, quality assurance, labeling, packaging, sterilization, storage, and shipping of our products. 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 QSR 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.

Our sources of supply for raw materials may 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 endeavor to 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.

Further, 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 the sale 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 their manufacturing capacity constraints, which may result in backlog in demand. Delays in filling orders (for example, if this supplier remains unable to meet our demand for acrylic lenses and we are unable to secure an alternative supply) can result in lost sales if alternative lenses 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 $130.8 million of U.S. federal tax net operating loss carryforwards as of January 2, 2015, 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 2017 and 2033. 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 in the U.S. 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.***

We conduct international operations through our subsidiaries. Tax laws affecting international operations are highly complex and subject to change. Our payment of income tax in the different countries where we operate depends in part on internal settlement prices and administrative charges among STAAR and our subsidiaries. These arrangements require judgments by us and are subject to risk that tax authorities will disagree with those judgments and impose additional taxes, penalties or interest on us. In addition, transactions that we have 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, which was the case during fiscal 2014 when we used $8.0 million of our cash for operations. 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 our 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, we 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.

***Because we manufacture most of our products from a single manufacturing site, if we suffer loss to our Monrovia facility due to catastrophe, or if our manufacturing sites fail to be in compliance with its regulatory approvals, our operations could be seriously harmed.***

We depend on the continuing operation of our manufacturing facility in Monrovia, California, which is currently our sole manufacturing facility for ICLs and IOLs. Our Monrovia facility could suffer catastrophic loss due to fire, flood, earthquake, terrorism or other natural or man-made disasters (including manufacturing challenges) and we would need resources (personnel and equipment) as well as additional regulatory approvals in order to manufacture our product at any second manufacturing site. 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, or if one of our manufacturing facilities is found not to be in compliance with regulatory requirements, it could disrupt our operations, delay production, shipments and revenue and result in large expenses to repair or replace the facility, as well as lost customers or sales. 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, which we refer to as the Swiss Plan and the Japan Plan, respectively. Both plans are underfunded and may require significant cash payments. During 2014, we contributed $241,000 to our Swiss Plan and made benefit payments of $1.1 million; although we did not contribute to our Japan Plan, we made benefit payments of $55,000.

As part of the Amendment of the Japan Plan discussed in Note 10 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 operating cashflows. 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.

We determine our 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 $3.1 million ($1.0 million for the Japan Plan and $2.1 million for the Swiss Plan) as of January 2, 2015.

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.

***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. We depend on our information technology infrastructure for electronic communications among our locations around the world and between our personnel and our subsidiaries, customers, and suppliers. We collect and retain large volumes of internal and customer, vendor and supplier data, including some personally identifiable information, for business purposes. We also maintain personally identifiable information about our employees. The integrity and protection of our customer, vendor, supplier, employee and other Company data is critical to our business. The regulatory environment governing information, security and privacy laws is increasingly demanding and continues to evolve. Maintaining compliance with applicable security and privacy regulations may increase our operating costs or adversely affect our business operations.

Unauthorized parties may also attempt to gain access to our systems or facilities through fraud, trickery or other forms of deceiving our team members, contractors and temporary staff. Security breaches could disrupt our operations, and we could suffer substantial financial damage or loss because of lost or misappropriated information. Despite the security measures we have in place, our facilities and systems, and those of our suppliers, distributors and customers with which we do business, may be vulnerable to security breaches, cyber-attacks, acts of vandalism, computer viruses, misplaced or lost data, programming and/or human errors or other similar events. Any security breach involving the misappropriation, loss or other unauthorized disclosure of confidential customer, employee, supplier or

Company information, whether by us or by our suppliers, distributors and customers with which we do business, could result in losses, damage our reputation, expose us to the risks of litigation and liability, disrupt our operations and have a material adverse effect on our business, results of operations and financial condition. 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 us 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.

***The increased use of social media platforms and mobile technologies presents new risks and challenges.***

New technologies are increasingly used to communicate about our products and the health conditions they are intended to treat. The use of these media requires specific attention and monitoring. For example, patients may use these channels to comment on the effectiveness of a product and to report an alleged adverse event. Negative posts or

comments about us or our business on any social networking web site could harm our reputation. In addition, our employees may use the social media tools and mobile technologies inappropriately, which may give rise to liability, or which could lead to the exposure of sensitive information. In either case, such uses of social media and mobile technologies could have a material adverse effect on our business, financial condition and results of operations.

**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 may, on our own initiative, initiate actions, including a non-reportable market withdrawal or a reportable product recall, relabeling or correction, for the purpose of correcting a material deficiency, improving device performance, or other reasons. In addition, the FDA and similar foreign health or governmental agencies have the authority to require an involuntary recall of commercialized products in the event of material deficiencies or defects in design, manufacturing or labeling or in the event that a product poses an unacceptable risk to health. In the case of the FDA, the authority to require a recall must be based on an FDA finding that there is a reasonable probability that a device intended for human use would cause serious, adverse health consequences or death.

We have voluntarily recalled our products and similar recalls could take place again. We may also be subject to recalls initiated by manufacturers of products we distribute. We believe that in recent years we have been less affected by recalls than most of our 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, the underlying causal issues, and the damage to our reputation, could cause professionals to discontinue using our products.

Companies are required to maintain certain records of actions, even if they determine such actions are not reportable to the FDA. If we determine that certain actions do not require notification of the FDA, the FDA may disagree with our determinations and require us to report those actions as recalls. A future recall announcement could harm our reputation with customers and negatively affect our sales. In addition, the FDA could take enforcement action for failing to report the recalls when they were conducted or failing to timely report or initiate a reportable product action. Moreover, depending on the corrective action we take to redress a product's deficiencies or defects, the FDA may require, or we may decide, that we will need to obtain new approvals or clearances for the device before we may market or distribute the corrected device. Seeking such approvals or clearances may delay our ability to replace the recalled devices in a timely manner. Moreover, if we do not adequately address problems associated with our devices, we may face additional regulatory enforcement action, including FDA warning letters, product seizure, injunctions, administrative penalties, or civil or criminal fines or prosecutions.

***If our products, or malfunction of our products, cause or contribute to a death or a serious injury, we will be subject to medical device reporting regulations, which can result in voluntary corrective actions or agency enforcement actions.***

Under the FDA regulations, we are required to report to the FDA any incident in which our product may have caused or contributed to a death or serious injury or in which our product malfunctioned and, if the malfunction were to recur, would likely cause or contribute to death or serious injury. In addition, all manufacturers placing medical devices in European Union markets are legally bound to report any serious or potentially serious incidents involving devices they produce or sell to the relevant authority in whose jurisdiction the incident occurred. We anticipate that in the future we will experience events that would require reporting to the FDA pursuant to the MDR regulations. Any adverse event involving our products could result in future voluntary corrective actions, such as product actions or customer notifications, or agency actions, such as inspection, mandatory recall or other enforcement action. Any corrective action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit, will require the dedication of our time and capital, distract management from operating our business, and may harm our reputation and financial results.

The decision to file an MDR involves a judgment by us as the manufacturer. We have made decisions that certain types of events are not reportable under the MDR regulations; however, there can be no assurance that the FDA will agree with our decisions. If we fail to report MDRs to the FDA within the required timeframes, or at all, or if the FDA disagrees with any of our determinations regarding the reportability of certain events, the FDA could take enforcement actions against us, which could have an adverse impact on our reputation and financial results.

***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 16.5% of our sales on research and development, including FDA-related panel, remediation, and inspection costs, during the fiscal year ended January 2, 2015. 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 coverage and reimbursement for our products by third-party payers 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 payers in both government and the private sector continue to seek to manage costs by restricting the types of procedures they cover to those viewed as most cost-effective and by capping or reducing reimbursement rates. Whether they limit reimbursement rates for our products or limit the surgical fees for a procedure that uses our products, these policies can reduce the sales volume of our covered 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. In the U.S. the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, the Health Care Reform Law, is expected to significantly change the system of public and private health care reimbursement. The Health Care Reform Law includes, among other things, a 2.3% excise tax on medical devices sold in the U.S., which applies to sales of our IOLs. In addition, other legislative changes have been proposed and adopted since the Health Care Reform Law was enacted. On August 2, 2011, the Budget Control Act of 2011 was signed into law, which, among other things, creates the Joint Select Committee on Deficit Reduction to recommend proposals in spending reductions to Congress. The Joint Select Committee did not achieve a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, triggering the legislation's automatic reduction to several government programs. This included aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect on April 1, 2013. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers.

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.

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

We are 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, the Centers for Medicare & Medicaid 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 design, pre-clinical and clinical testing, clearance or 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 *"Item 1. Business—Regulatory Matters"* section of this Annual 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 clearance or approval. Obtaining

clearance or approval can be a long and expensive process, and clearance or 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 granting clearance or 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 clearance or approval and may never gain clearance or approval. The FDA can delay, limit or deny clearance or approval of a device for many reasons, including:

- we may not be able to demonstrate to the FDA's satisfaction that our products are safe and effective for their intended uses;
- the data from our pre-clinical studies and clinical trials may be insufficient to support clearance or approval, where required; and
- the manufacturing process or facilities we use may not meet applicable requirements.

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 clears or approves a product, the clearance or 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 clearance or approval of our new products, or if the clearance or approval is too narrow, we will not be able to market these products, which would eliminate or reduce our potential sales and earnings.

In addition, the FDA and other regulatory authorities may change their clearance and approval policies, adopt additional regulations or revise existing regulations, or take other actions which may prevent or delay approval or clearance of our products under development or impact our ability to modify our currently cleared products on a timely basis. For example, in response to industry and healthcare provider concerns regarding the predictability, consistency and rigor of the 510(k) regulatory pathway, the FDA initiated an evaluation of the program, and in January 2011, announced several proposed actions intended to reform the review process governing the clearance of medical devices. The FDA intends these reform actions to improve the efficiency and transparency of the clearance process, as well as bolster patient safety. In addition, as part of FDASIA, Congress reauthorized the Medical Device User Fee Amendments with various FDA performance goal commitments and enacted several "Medical Device Regulatory Improvements" and miscellaneous reforms which are further intended to clarify and improve medical device regulation both pre- and post-approval.

Even after we have obtained the proper regulatory clearance or approval to market a product, we have ongoing responsibilities under FDA regulations. The failure to comply with applicable regulations could jeopardize our ability to sell our products and result in enforcement actions such as warning letters, fines, injunctions, civil penalties, termination of distribution, recalls or seizures of products, delays in the introduction of products into the market, total or partial suspension of production, refusal to grant future clearances or approvals, withdrawals or suspensions of current clearances or approvals resulting in prohibitions on sales of our products, and criminal penalties. Any of these sanctions could result in higher than anticipated costs or lower than anticipated sales and have a material adverse effect on our reputation, business, results of operations and financial condition.

***Modifications to our products may require new 510(k) clearances or PMA approvals, or may require us to cease marketing or recall the modified products until clearances or approvals are obtained.***

Any modification to a 510(k)-cleared device that could significantly affect its safety or effectiveness, including any significant change in design or manufacture, or that would constitute a major change in its intended use, requires a new 510(k) clearance or, possibly, approval of a PMA. The FDA requires every manufacturer to make this determination in the first instance, but the FDA may review any manufacturer's decision. The FDA may not agree with our decisions regarding whether new clearances or approvals are necessary. We have modified some of our 510(k) cleared products, and have determined based on our review of the applicable FDA guidance that in certain instances new 510(k) clearances or pre-market approvals are not required. If the FDA disagrees with our determination and requires us to submit new 510(k) notifications or PMAs for modifications to our previously cleared products for which we have concluded that new clearances or approvals are unnecessary, we may be required to cease marketing or to recall the modified product until we obtain clearance or approval, and we may be subject to significant regulatory fines or penalties.

Furthermore, the FDA's ongoing review of the 510(k) program may make it more difficult for us to make modifications to our previously cleared products, either by imposing more strict requirements on when a manufacturer must submit a new 510(k) for a modification to a previously cleared product, or by applying more onerous review criteria to such submissions. Specifically, on July 9, 2012, FDASIA was enacted, which, among other requirements,

obligated the FDA to prepare a report for Congress on the FDA's approach for determining when a new 510(k) will be required for modifications or changes to a previously cleared device and to wait at least a year following submission of this report to issue revised guidance for industry on this topic. FDA submitted its report to Congress in January 2014and is expected to issue draft revised guidance for public comment at some time in the future prior to issuing final guidance for implementation. Until the FDA issues final, revised guidance to assist device manufacturers in determining when to submit a new 510(k) for a change or modification to a previously cleared device, manufacturers may continue to adhere to the FDA's 1997 Guidance on this topic when making this determination, but the practical impact of the FDA's continuing and evolving scrutiny of these issues remains unclear.

***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 which 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. These laws and regulations act to limit our marketing practices, require the dedication of resources to ensure compliance, and expose us to additional liabilities.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. In addition, recent health care reform legislation has strengthened these laws. For example, 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.

There has also been a recent trend of increased federal and state regulation of payments made to physicians. The Health Care Reform Law imposed new reporting requirements on device manufacturers for payments made by them and in some cases, their distributors, to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members, commonly known as the Physician Payment Sunshine Act. Failure to submit required information may result in civil monetary penalties of up to an aggregate of $150,000 per year (or up to an aggregate of $1 million per year for “knowing failures”), for all payments, transfers of value or ownership or investment interests that are not timely, accurately and completely reported in an annual submission. Device manufacturers were required to begin collecting data on August 1, 2013 and must submit reports to CMS by March 31, 2014, and by the 90th day of each subsequent calendar year.

Certain states also mandate implementation of commercial compliance programs, impose restrictions on device manufacturer marketing practices and/or require the tracking and reporting of gifts, compensation and other remuneration to physicians. The shifting commercial compliance environment and the need to build and maintain robust and expandable systems to comply with different compliance and/or reporting requirements in multiple jurisdictions increase the possibility that a healthcare company may violate one or more of the requirements.

Achieving and sustaining compliance with these laws may prove costly. In addition, any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management’s attention from the operation of our business. If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, the exclusion from participation in federal and state healthcare programs, imprisonment, or the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business, our reputation and our financial results.

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 we are 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 us of its findings and may not inform us that the inquiry has been terminated.

As required by the Sarbanes-Oxley Act of 2002, we maintain a hotline for employees to report any violation of laws, regulations or company policies anonymously, which is intended to permit us 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 our policies or applicable laws or regulations have been violated, we may find it necessary to conduct our 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 we sell our products, doctors, including ophthalmologists, are employees of the government, government-sponsored enterprises or large health maintenance organizations. In the past, 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 our 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. Also, several of our patents expire within the next couple of years, which may expose our technologies to competitors. 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

- re-design 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, some of which will expire this year, 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 or propose other business.

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

We are generally 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, we have 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 $200 million in equity or debt securities or any combination of such securities. While we currently have 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. The closing price of our common stock ranged from $8.60 to $19.35 per share during the year ended January 2, 2015. 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 common stock.

***Because we do not intend to pay dividends, stockholders will benefit from an investment in our common stock only if it appreciates in value.***

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 do not expect 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 our earnings, financial condition, capital needs and other factors deemed relevant by the Board of Directors, and may be restricted by future agreements with lenders. As a result, the success of an investment in our common stock will depend entirely upon any future appreciation. There is no guarantee that our common stock will appreciate in value or even maintain the price at which stockholders have purchased their shares.

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 capabilities, 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 in Shin-Urayasu, Japan and a final packaging and distribution facility in Ichikawa City, Japan. We believe our operating facilities in the U.S., Switzerland and Japan are suitable and adequate for our current and future planned requirements. The Company could increase capacity in our Monrovia, California facility by adding additional shifts.

Item 3. Legal Proceedings

From time to time the Company may be 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. The most significant of these actions, proceedings and investigations are described below. STAAR maintains insurance coverage for product liability and certain securities. Legal proceedings can extend for several years, and the matters described below concerning the Company are at very early stages of the legal and administrative process. As a result, these matters have not yet progressed sufficiently through discovery and/or development of important factual information and legal issues to enable the Company to determine whether the proceedings are material to the Company or to estimate a range of possible loss, if any. Unless otherwise disclosed, the Company is unable to estimate the possible loss or range of loss for the legal proceedings described below. While it is not possible to accurately predict or determine outcomes of these items, an adverse determination in one or more of these items currently pending could have a material adverse effect on the Company’s consolidated results of operations, financial position or cash flows.

***Securities and Exchange Commission Informal Inquiry***

In a letter dated July 3, 2014, the United States Securities and Exchange Commission (“SEC”) advised STAAR that it is conducting an informal inquiry into compliance with U.S. securities laws. The letter requested documents concerning any FDA inspections, investigations, observations, noted violations, or warnings since January 1, 2014. The Company is cooperating with this informal inquiry.

***Todd v. STAAR***

On July 8, 2014, a putative securities class action lawsuit was filed by Edward Todd against STAAR and three officers in the federal court located in Los Angeles, California. The plaintiff claims that STAAR made misleading statements to and omitted material information from our investors between February 27, 2013 and June 30, 2014 about alleged regulatory violations at STAAR's Monrovia manufacturing facility. On July 21, 2014, the Company was served with the Complaint. Although the ultimate outcome of this action cannot be determined with certainty, the Company believes that the allegations in the Complaint are without merit. The Company intends to vigorously defend against this lawsuit. The Company intends to file a motion to dismiss the complaint, when appropriate, in the ongoing proceeding. On October 20, 2014, plaintiff amended its complaint, dismissed two Company officers, added one other officer, and reduced the alleged Class Period to November 1, 2013 to June 30, 2014.

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 January 2, 2015 | | |
| Fourth Quarter | $11.50 | $8.60 |
| Third Quarter | 13.77 | 10.03 |
| Second Quarter | 19.35 | 13.85 |
| First Quarter | 19.05 | 14.14 |
| Year ended January 3, 2014 | | |
| Fourth Quarter | $16.23 | $12.41 |
| Third Quarter | 13.23 | 10.41 |
| Second Quarter | 10.51 | 5.31 |
| First Quarter | 6.25 | 5.20 |

***Holders***

As of February 10, 2015, there were approximately 406 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 January 1, 2010 through January 2, 2015 of the total performance of the following:

- STAAR Surgical Company;

- the Nasdaq Stock Market;

- a peer group we have selected consisting of 10 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); 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 January 1, 2010 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: | 2009 | 2010 | 2011 | 2012 | 2013 | 2014 |
|---|---|---|---|---|---|---|
| STAAR Surgical Company | 100.00 | 196.77 | 338.39 | 187.74 | 519.35 | 291.29 |
| The Nasdaq Stock Market (US and Foreign Companies | 100.00 | 118.02 | 117.02 | 134.80 | 190.51 | 220.35 |
| Proxy Peer Group | 100.00 | 117.75 | 94.24 | 104.33 | 136.07 | 147.93 |

**Notes:**

A. The lines represent monthly index levels derived from compounded daily returns that include all dividends.
B. This indexes are reweighted daily, using the market capitalization pm 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 $100.00 on 1/1/2010.

Item 6. Selected Financial Data

The following table sets forth selected consolidated financial data with respect to the five most recent fiscal years ended January 2, 2015, January 3, 2014, December 28, 2012, December 30, 2011, and December 31, 2010. The selected consolidated statement of operations data set forth below for each of the three most recent fiscal years, and the selected consolidated balance sheet data set forth below at January 2, 2015 and January 3, 2014 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 December 30, 2011 and December 31, 2010 and the consolidated balance sheet data set forth below at December 28, 2012, December 30, 2011, and December 31, 2010, are derived from audited consolidated financial statements of the Company not included in this Annual Report. The selected consolidated financial data should be read in conjunction with the consolidated financial statements of the Company, and the Notes thereto, included in this Annual Report, and "*Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.*"

| | Fiscal Year Ended | | | | |
|---|---|---|---|---|---|
| | January 2, 2015 | January 3, 2014 | December 28, 2012 | December 30, 2011 | December 31, 2010 |
| | (In thousands except per share data) | | | | |
| Statement of Operations | | | | | |
| Net sales | $74,987 | $72,215 | $63,783 | $62,765 | $54,958 |
| Cost of sales | 26,164 | 21,906 | 19,492 | 20,396 | 19,882 |
| Gross profit | 48,823 | 50,309 | 44,291 | 42,369 | 35,076 |
| General and administrative | 18,160 | 16,568 | 15,150 | 14,932 | 14,778 |
| Marketing and selling | 25,879 | 23,888 | 21,281 | 17,726 | 17,176 |
| Research and development | 12,363 | 6,708 | 6,444 | 5,868 | 5,724 |
| Medical device tax | 127 | 203 | — | — | — |
| Other general and administrative expenses | 321 | 2,242 | 2,636 | 1,060 | — |
| Operating income (loss) | (8,027) | 700 | (1,220) | 2,783 | (2,602) |
| Total other income (expense), net | (618) | 414 | 701 | (79) | (1,079) |
| Income (loss) before income taxes | (8,645) | 1,114 | (519) | 2,704 | (3,681) |
| Income tax provision (benefit) | (253) | 716 | 1,244 | 1,356 | 432 |
| Income (loss) from continuing operations | (8,392) | 398 | (1,763) | 1,348 | (4,113) |
| Income from discontinued operations, net of income taxes | — | — | — | — | 4,166 |
| Net income (loss) | $(8,392) | $398 | $(1,763) | $1,348 | $53 |
| Income (loss) per share from continuing operations – basic | $(0.22) | $0.01 | $(0.05) | $0.04 | $(0.12) |
| Income (loss) per share from continuing operations – diluted | $(0.22) | $0.01 | $(0.05) | $0.04 | $(0.12) |
| Income per share from discontinued operations, basic and diluted | $— | $— | $— | $— | $0.12 |
| Net income (loss) per share – basic | $(0.22) | $0.01 | $(0.05) | $0.04 | $(.00) |
| Net income (loss) per share – diluted | $(0.22) | $0.01 | $(0.05) | $0.04 | $(.00) |
| Weighted average shares outstanding-basic | 38,091 | 36,706 | 36,253 | 35,434 | 34,825 |
| Weighted average shares outstanding –diluted | 38,091 | 38,607 | 36,253 | 36,878 | 34,825 |
| Balance Sheet Data | | | | | |
| Working capital | $28,451 | $31,663 | $26,125 | $24,638 | $16,539 |
| Total assets | 58,911 | 61,931 | 54,759 | 49,006 | 40,585 |
| Long-term obligations | 5,366 | 4,667 | 5,068 | 5,532 | 4,711 |
| Stockholders' equity | 37,099 | 38,852 | 31,742 | 29,458 | 22,427 |

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 about any of the following: any projections of earnings, revenue, sales, profit margins, cash, effective tax rate or any other financial items; the plans, strategies, and objectives of management for future operations or prospects for achieving such plans; statements regarding new, existing, or improved products, including but not limited to, expectations for success of new, existing, and improved products in the U.S. or international markets or government approval of a new or improved products (including the Toric ICL in the U.S.); or commercialization of new or improved products; the nature, timing and likelihood of resolving issues cited in the FDA’s 2014 Warning Letter or 2015 FDA-483; future economic conditions or size of market opportunities; expected costs of quality system remediation efforts; expected costs and savings from business consolidation plans and the timetable for those plans; statements of belief, including as to achieving 2015 growth plans or metrics; expected regulatory activities and approvals, product launches, and any statements of assumptions underlying any of the foregoing.*

*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 2014 Key Operational Metrics*

Two principal strategic goals guided STAAR's key operational metrics in 2014: to lay the groundwork for further growth and to achieve and maintain profitability. In pursuit of these goals, STAAR aligned its business initiatives during 2014 along five key annual metrics that it used to gauge its performance for the year. These metrics are as follows:

· Increase total revenue by 8% to 10%.

- As discussed below in "*—Results of Operations*," our total revenue increased by 3.8% for the full year of 2014.

· Increase ICL Sales by 20% for the full year.

- As discussed below in "*—Results of Operations*," ICL sales declined by 0.2% for the full year.

- Increase gross profit margins by 300 basis points to 72.7% for the full year.

- As discussed below in "*—Results of Operations*," gross profit margin decreased by 460 basis points to 65.1% for the full year.

- Achieve profitability on a GAAP basis for the full year.

- As discussed below in "*—Results of Operations*," we reported a net loss of $8.4 million for the full year.

- Manage the manufacturing consolidation with no material disruption to customer supply requirements or quality.

- We completed the planned transfer of manufacturing from our Nidau, Switzerland location, completing the consolidation of our international manufacturing sites. We maintain manufacturing capability at that location. We are currently experiencing manufacturing challenges in Monrovia that is causing product backlogs for ICLs and we are addressing the matter.

***Other Highlights***

*General*

In 2014, total ICL sales declined 0.2% primarily due to backorders. Backorders were the result of manufacturing challenges in the Monrovia facility that we are addressing. Also, we implemented a voluntary hold on over 2,000 ICLs from shipment at the end of the quarter. The impact of these manufacturing challenges in the fourth quarter of 2014 was approximately $1.0 million. We expect to reduce the backlog to customary levels by the end of the second quarter of 2015. Increased ICL sales in 8 out of 12 of the Company's focused markets were offset by decreases in Korea, the U.S., and Japan. Negative media attention in Korea regarding refractive procedures – primarily LASIK – decreased the demand for refractive procedures generally and the extent of that impact is currently uncertain. In 2014, total IOL sales increased 0.8% due to increased sales of acrylic preloaded IOLs largely offset by lower silicone IOL sales (including preloaded silicone) in Japan, the U.S., and China, and lower collamer IOL sales in the U.S. Total sales of our other product category increased, primarily due to an increase in preloaded injector parts sold to a third party manufacturer. Changes in foreign currency negatively impacted total sales by approximately $1.6 million. Gross profit decreased 3.0% due to decreased ICL sales, high manufacturing costs due to the transition of manufacturing from Switzerland to the U.S., and higher inventory provisions.

The Company has generally been able to maintain the average selling prices for its products in the face of downward pricing pressure in the healthcare industry. Global economic conditions may continue to negatively impact the number of refractive procedures performed.

We expect revenue growth over the next 12 months and a related positive impact on gross margin and earnings. This growth is expected to be driven primarily by increased sales of our ICL and preloaded acrylic IOL products. In addition, we expect continued investment in our quality systems and research and development. We expect sales of lower margin injector parts to continue to our lens supplier for their preloaded injector which they sell under their own brand. We will continue our focus on prudently managing our business and delivering solid financial results, while at the same time striving to continue to introduce new products to the market. Finally, we will continue to evaluate opportunities to acquire new product lines, technologies and companies.

Product development activities are inherently uncertain, and there can be no assurance that we will be able to obtain approval for any of our products, or if we obtain approval that we will successfully commercialize any of our products.

We completed the planned transfer of manufacturing from our Nidau, Switzerland location to Monrovia, California. In December 2014, the FDA approved STAAR's PMA Supplement regarding its calculator software for the ICL, which enables physicians to calculate lens power and length as well as place lens orders with STAAR. In November 2014, the China Food and Drug Administration (CFDA) issued an Approved Certification, which finalized the approval process for our Visian ICL with CentraFLOW technology for marketing and sale in China. As a business in a highly regulated and competitive industry, we face many risks and challenges. You should refer to the discussion in Item 1A, "Risk Factors" in Part I of this Annual Report for further discussion of risks related to our business.

*Global Visian ICL and TICL Sales*

STAAR is the only company with approval to sell a posterior chamber phakic IOL, known as the ICL in the U.S. In 2014, global sales of the ICL products represented approximately 59% of STAAR's business. We focus our ICL marketing and sales efforts in the top twelve refractive markets, based on the success of our focused market strategy since 2010. These markets include the U.S., Japan, Korea, China, India, Spain, Middle East, Germany, France, Italy, U.K., and Latin America.

In September 2011, we launched the V4c model of the ICL with CentraFLOW technology, featuring 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. By simplifying the procedure

and increasing patient comfort, the ICL with CentraFLOW technology makes the visual outcomes of the ICL available through a surgical implantation experience closer to LASIK, which we believe attracts 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.

In 2013, the ICL with CentraFLOW technology received regulatory approval in Korea, India and Argentina. In 2014, ICL with CentraFLOW technology received regulatory approval in Japan and China. We believe these approvals helped increase sales, improved the competitiveness of the ICL product line and will help move us closer to our 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. In March 2014, we received favorable votes by FDA Ophthalmic Devices Panel of the Medical Devices Advisory Committee regarding the TICL's safety and effectiveness. In May 2014, we received a Warning Letter from the FDA citing alleged violations of current good manufacturing practice ("cGMP") regulations that were identified by the FDA during an inspection of the Company's manufacturing facility in Monrovia, California. We continue to devote considerable resources to addressing the issues raised in the still-outstanding 2014 Warning Letter and 2015 FDA-483. During 2014, we spent approximately $1.8 million on our remediation efforts and expect this to increase to approximately $4 million in 2015 and that these efforts will continue into 2016. We cannot predict when, or if, the FDA may grant approval of the Toric ICL. (*See, "Item 1.—Business—Regulatory Matters—Regulatory Requirements in the United States."*). On October 9, 2012, STAAR submitted a clinical study protocol regarding the ICL with CentraFLOW technology. On December 12, 2013, we met with the FDA in Washington D.C. to discuss the protocol and we remain in dialogue with the FDA regarding a revised proposed protocol.

Research and Development efforts continued on developing a presbyopia-correcting ICL for myopic and astigmatic patients. Currently efforts focus on one presbyopia-correcting technology early onset and progression of presbyopia by providing an additional 1.0 to 2.0 diopter of near correction, and another technology for patient in their forties and older that require a greater addition to correct presbyopia. We continued development of our preloaded ICL product, which received CE Mark in 2014, but requires additional design work prior to transferring to production.

*Global IOL Sales.*

STAAR pioneered the development of folding lenses for use in cataract surgery, and IOLs represented approximately 33% of STAAR's business in 2014.

In the fourth quarter of 2012, STAAR launched in Japan and select markets in Europe a hydrophobic acrylic, bluelight filter, preloaded IOL, featuring the popular single-piece IOL format, known as the KS-SP. The market favorably received the KS-SP and we expect demand to remain high. After several quarters where our third-party acrylic lens supplier could not manufacture sufficient quantity of lenses to satisfy demand, over the last two quarters of 2014, they have met demand. We expect them to meet demand in 2015. In the first quarter of 2015, our third party acrylic lens supplier identified higher than expected reject rates with our injectors, manufactured for us by a third party injector manufacturer, used for the pre-loaded KS-SP product line. We anticipate that this issue will impact our sales of injectors to our third party acrylic lens supplier during the first quarter of 2015. We still are exploring the matter to determine the extent of exposure, if any. Based on the information we have to date, we believe this matter is isolated and is not material to our 2014 financial statements.

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

- we plan to expand our preloaded IOL offering to our collamer IOL line;
- we plan to expand sales of the preloaded acrylic IOL in Europe through increased sales and marketing activities and entering new markets; 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 and Tax Strategy.* Since 2011, STAAR devoted significant resources to two initiatives: to consolidate global manufacturing, and to optimize our global organization for tax purposes. The goal of these strategies is to improve upon gross profit margins by streamlining operations, thereby reducing costs and to increase profits in the U.S. to enable us to utilize our $130.8 million in net operating loss carryforwards, and at the same time, reduce income taxes in foreign jurisdictions where we pay tax.

In December 2012, the Company began manufacturing the first ICLs in the U.S., whereas they were previously exclusively manufactured in Switzerland. In 2014, we ceased manufacturing ICLs in our Swiss facility, and all ICLs are manufactured in the U.S. Our manufacturing consolidation, which is subject to significant risks, is further described under "*Item 1A. Risk Factors—Risks Related to Our Business—Our manufacturing consolidation plan exposes us to risk."*

STAAR has spent approximately $6.3 million on its manufacturing consolidation initiatives over a three and a half-year period and spent approximately $0.3 million during 2014. Expenditures to date have largely consisted of severance, employee costs, and professional fees to advisors and consultants.

In addition, as STAAR's profitability grows outside the U.S., its liability for income taxes in various jurisdictions has also increased. STAAR has developed a strategy to reduce its future tax liabilities as its business grows. Among other things, STAAR seeks to utilize the approximately $130.8 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.*

Manufacturing the ICL is a complex process, and 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. Challenges in manufacturing the ICL, such as we are currently experiencing, causes delays in filling orders, which 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 the fourth quarter of 2014, we experienced a backlog for ICLs and TICLs primarily due to manufacturing challenges in our Monrovia facility. Also, we implemented a voluntary hold on over 2,000 ICLs from shipment at the end of the quarter. The impact of these manufacturing challenges to our revenue in the fourth quarter of 2014 was approximately $1.0 million We continue to address our manufacturing challenges in our Monrovia facility and expect to reduce the backlog to customary levels by the end of the second quarter of 2015. If we cannot resolve our manufacturing challenges during the first two quarters of 2015, our financial results may be adversely impacted.

*Status of U.S. TICL Submission.*

Regarding our PMA Supplement submission to the FDA seeking approval of the TICL, on March 14, 2014, a FDA Ophthalmic Devices Panel of the Medical Devices Advisory Committee voted favorably in response to the three questions posed to it by the FDA's Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices (regarding the TICL's safety and effectiveness as well as whether the TICL's benefits outweigh its risks). The FDA has not provided us with a timeline for follow-up after the advisory panel meeting regarding a timeline for a decision on the PMA Supplement for the TICL, which has remained pending for over eight years. While the PMA supplement remains pending, we cannot predict when, or if, the FDA will grant approval of the TICL for use in the United States.

As discussed in Item IA, "Risk Factors" under the heading – "*FDA compliance issues have delayed approvals and we expect to devote significant resources to maintaining compliance in the future,"* on May 27, 2014, we received the 2014 Warning Letter from the FDA citing alleged violations of current good manufacturing practice ("cGMP") regulations that were identified by the FDA during an inspection of the Company's manufacturing facility in Monrovia, California between February 10, 2014 and March 21, 2014. To summarize, the 2014 Warning Letter observations require remedial action in four general areas: design control documentation; validation of software for an on-line calculator; data collection and trending of ICL vault complaints; and shelf life data on the ICL product. The 2014 Warning Letter provides that, until the Company addresses the deficiencies to the FDA's satisfaction, the FDA will not approve PMAs for the Company's Class III devices where the applications are reasonably related to the cGMP violations cited in the Warning Letter. On October 15, 2014 we responded to questions from the FDA regarding the method used to select ICL power and length. Beginning on November 14, 2014 and continuing through February 4, 2015, the FDA inspected our Monrovia facility. On February 4, 2015, at the conclusion of the inspection, the FDA issued the 2015 FDA-483 with ten inspectional observations. The observations focus primarily on the need for adherence to and improved procedures, processes and documentation relating to design change, design transfer into specifications and production, verification and validation associated with device design and production, improvement in good documentation practices, and broader environmental monitoring. STAAR responded to the FDA-483 and is concurrently continuing to develop and implement its corrective action plans relating to the 2014 Warning Letter and the 2015 FDA-483. While the PMA supplement remains pending, we cannot predict when, or if, the FDA will grant approval of the TICL for use in the United States.

**Results of Operations**

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

| | Percentage of Net Sales | | | Percentage Change | |
|---|---|---|---|---|---|
| | January 2, 2015 | January 3, 2014 | December 28, 2012 | 2014 vs. 2013 | 2013 vs. 2012 |
| Net sales | 100.0% | 100.0 % | 100.0 % | 3.8 % | 13.2 % |
| Cost of sales | 34.9 % | 30.3 % | 30.6 % | 19.4 % | 12.4 % |
| Gross profit | 65.1 % | 69.7 % | 69.4 % | (3.0 )% | 13.6 % |
| General and administrative | 24.2 % | 22.8 % | 23.7 % | 9.2 % | (9.4 )% |
| Marketing and selling | 34.5 % | 33.1 % | 33.4 % | (8.3 )% | (12.3 )% |
| Research and development | 16.5 % | 9.3 % | 10.1 % | 84.8 % | (4.1 )% |
| Medical device tax | 0.2 % | 0.3 % | - % | 37.4 % | * |
| Other general and administrative expenses | 0.4 % | 3.1 % | 4.1 % | 85.7 % | 14.9 % |
| Operating income (loss) | (10.7 )% | 1.1 % | (1.9 )% | * | * |
| Total other income (expense), net | (0.8 )% | 0.7 % | 1.1 % | * | (40.9 )% |
| Income (loss) before income taxes | (11.5 )% | 1.8 % | (0.8 )% | * | * |
| Provision for income taxes | (0.3 )% | 1.0 % | 2.0 % | * | 42.4 % |
| Net income (loss) | (11.2 )% | 0.8 % | (2.8 )% | * | * |

* Denotes change is greater than 100%

***Net Sales***

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

| | | 2014 | % of Total | 2013 | % of Total | 2012 |
|---|---|---|---|---|---|---|
| ICL | 58.7 % | $44,047 | 61.2 % | $44,128 | 55.0 % | $35,080 |
| IOL | 32.5 % | 24,336 | 33.4 % | 24,153 | 40.7 % | 25,971 |
| Core Product Sales | 91.2 % | 68,383 | 94.6 % | 68,281 | 95.7 % | 61,051 |
| Other | 8.8 % | 6,604 | 5.4 % | 3,934 | 4.3 % | 2,732 |
| Total Sales | 100.0% | $74,987 | 100.0% | $72,215 | 100.0% | $63,783 |

Net sales for 2014 were $75.0 million, a 3.8% increase over the $72.2 million reported in fiscal 2013. The increase in net sales was due to an increase in other product sales. Changes in foreign currency negatively impacted net sales by $1.6 million.

Net sales for 2013 were $72.2 million, a 13.2% increase over the $63.8 million reported in fiscal 2012. The increase in net sales was due to a 26% increase in ICL sales and a 44% increase in other product sales, partially offset by a 7% decrease in IOL sales. Changes in foreign currency negatively impacted net sales by $3.8 million.

Total ICL sales for 2014 were $44.0 million, a 0.2% decrease from $44.1 million reported for fiscal 2013. ICL sales increases in 8 out of 12 of the Company's focused markets were offset by decreases in Korea, the US, and Japan. Changes in foreign currency negatively impacted ICL sales by approximately $0.1 million. ICL sales represented 58.7% of our total sales for fiscal year 2014.

Total ICL sales for 2013 were $44.1 million, a 26% increase over the $35.1 million reported in fiscal 2012. ICL unit volume grew in each of the Company's top 12 markets and sales increased in 11 out of 12 markets with the only exception being Japan whose sales declined 4% due to the negative impact of foreign currency. ICL sales represented 61.2% of our total sales for fiscal 2013. Toric ICL sales represented 47% of total ICL sales, where approved.

Total IOL sales were $24.3 million for fiscal 2014, an increase of 0.8% over the $24.2 million reported in fiscal 2013. The increase is due to increased sales of acrylic preloaded IOLs largely offset by lower silicone IOL sales (including preloaded silicone) in Japan, the US, and China, and lower collamer IOL sales in the US. Changes in foreign currency negatively impacted IOL sales by approximately $1.1 million. IOL sales represented 32.5% of our total sales for fiscal year 2014.

Total IOL sales were $24.2 million for fiscal 2013, a 7.0% decrease from fiscal 2012 sales of $26.0 million. The decrease in IOL sales was primarily due to the negative impact of changes in foreign currency which reduced net sales of IOLs by $3.2 million. IOL sales represented 33% of the Company's total sales in fiscal 2013. Preloaded IOL sales represented 76% of total IOL sales in fiscal 2013.

Other product sales for the year ended January 2, 2015 were $6.6 million, a 67.9% increase compared to the $3.9 million reported for the year ended January 3, 2014. The increase in other product sales is due to an increase in preloaded injector part sales to a third party manufacturer for product they sell to their customers. Changes in foreign currency negatively impacted other product sales by approximately $0.4 million. Other product sales represented 8.8% of our total sales for fiscal year 2014.

Other product sales increased to $3.9 million in fiscal 2013 from $2.7 million in fiscal 2012. The increase in other product sales is due to an increase in preloaded injector part sales to a third party manufacturer for product they sell to their customers. Other product sales represented 5.4% of the Company's total sales in fiscal 2013.

***Gross Profit***

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

| | 2014 | 2013 | 2012 |
|---|---|---|---|
| Gross Profit | $48,823 | $50,309 | $44,291 |
| Gross Profit Margin | 65.1 % | 69.7 % | 69.4 % |

Gross profit for the year ended January 2, 2015 was $48.8 million, a 3.0% decrease compared to the $50.3 million reported for the year ended January 3, 2014. Gross profit margin decreased to 65.1% for the year, compared to 69.7% last year. The decrease in gross profit and gross profit margin is due to an increase in inventory reserves primarily related to Toric ICL inventory that was built in Switzerland in preparation for the U.S. launch. The reserves were recorded in accordance with Company policies regarding the timing of reserves for expiring inventory and projections for the timing and amount of sales during the same period. In addition, gross profit and gross profit margin decreased due to increased ICL manufacturing cost and an increased mix of low margin injector part sales.

Gross profit in fiscal 2013 was $50.3 million compared with $44.3 million in fiscal 2012. The increase in gross profit and gross profit margin was largely attributable to the 26% increase in ICL sales. Gross margin was negatively impacted by the increased sales of injector parts which reduced gross margin by 140 basis points and higher costs in

Japan for U.S. dollar sourced products due to a weaker yen which reduced gross margin by 120 basis points.

***General and Administrative Expense***

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

| | 2014 | | 2013 | | 2012 | |
|---|---|---|---|---|---|---|
| General and Administrative Expense | $18,160 | | $16,568 | | $15,150 | |
| Percentage of Sales | 24.2 | % | 22.8 | % | 23.7 | % |

General and administrative expense for the year ended January 2, 2015 was $18.2 million, a 9.6% increase compared to the $16.6 million reported for the year ended January 3, 2014. The increase in expense is due to increased consulting expense, legal fees, depreciation expense, and salaries and travel, partially offset by a decrease in stock based compensation.

General and administrative expense in fiscal 2013 was $16.6 million or 22.8% of sales, compared with $15.1 or 23.7% of sales in fiscal 2012. Although G&A expense has decreased as a percentage of sales, the increase in dollars was primarily due to an increased compensation expense and the costs associated with the new facility in California.

***Marketing and Selling Expense***

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

| | 2014 | | 2013 | | 2012 | |
|---|---|---|---|---|---|---|
| Marketing and Selling Expense | $25,879 | | $23,888 | | $21,281 | |
| Percentage of Sales | 34.5 | % | 33.1 | % | 33.4 | % |

Marketing and selling expense for the year ended January 2, 2015 was $25.9 million, an 8.3% increase compared to the $23.9 million reported for the year ended January 3, 2014. The increase in expense is due to increased trade show expense, online marketing expense, compensation and advertising and promotions.

Marketing and selling expense in fiscal 2013 was $23.9 million or 33.1% of sales, compared with $21.3 or 33.4% of sales in fiscal 2012. The increase in expense is due to increased compensation and travel costs primarily due to increased headcount, increased commissions due to increased sales, increased tradeshow expenses, and increased promotional activities including social media marketing efforts.

***Research and Development Expense***

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

| | 2014 | | 2013 | | 2012 | |
|---|---|---|---|---|---|---|
| Research and Development Expense | $12,363 | | $6,708 | | $6,444 | |
| Percentage of Sales | 16.5 | % | 9.3 | % | 10.1 | % |

Research and development expense for the year ended January 2, 2015 was $12.4 million, an 84.3% increase compared to the $6.7 million reported for the year ended January 3, 2014. The increase is due to FDA panel and remediation expenses of $3.3 million and increased headcount and new product development expenses. The Company expects its remediation efforts to continue through 2016 and estimates it will incur costs of approximately $4 million in 2015 related to these activities.

Research and development expense in fiscal 2013 was $6.7 million or 9.3% of sales, compared with $6.4 million or 10.1% of sales in fiscal 2012. The increase in expense is due to new product development and costs of preparing for the Toric ICL Panel meeting scheduled by the FDA for March 14, 2014.

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.

***Other General and Administrative Expenses***

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

| | 2014 | 2013 | 2012 |
|---|---|---|---|
| Other General and Administrative Expenses | $321 | $2,242 | $2,636 |
| Percentage of Sales | 0.4 % | 3.1 % | 4.1 % |

Other general and administrative expenses in fiscal 2014 of $0.3 million compared with $2.2 million in fiscal 2013 represent costs associated with the Company’s consolidation of its manufacturing operations. During 2014, the Company completed the consolidation of Nidau, Switzerland manufacturing to the U.S.

Other general and administrative expenses in fiscal 2013 of $2.2 million compared with $2.6 million in fiscal 2012 represent costs associated with the Company’s project to consolidate its manufacturing operations to the U.S. During 2013, the Company completed the consolidation and closure of Japan manufacturing.

***Other Income (Expense), Net***

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

| | 2014 | 2013 | 2012 |
|---|---|---|---|
| Other Income (Expense), net | $(618) | $414 | $701 |
| Percentage of Sales | (0.8)% | 0.7 % | 1.1 % |

Other expense for the year ended January 2, 2015 was $0.6 million, compared to the $0.4 million of other income reported for the year ended January 3, 2014, and $0.7 million of other income for the year ended December 28, 2012. The change in other income and expense is due primarily to exchange losses recorded during the period compared to exchange gains reported in the same period last year.

Other income (expense), net generally relates to interest expense on notes payable and capital 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) | |
|---|---|---|
| | 2014 v. 2013 | 2013 v. 2012 |
| Interest income | $(8) | $— |
| Interest expense | 16 (1) | 121 |
| Exchange gains (losses) | (935) | (72) |
| Royalty income | (67) | 85 |
| Fair value adjustment of warrants[2] | — | (308) |
| Other | (38) | (113) |
| Net change in other income (expense), net | $(1,032) | $(287) |

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

(2) Relates to the fair value of 70,000 warrants issued to Broadwood Partners, L.P. on March 21, 2007. The warrants expired unexercised on March 21, 2013.

***Provision (Benefit) for Income Taxes***

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

| | 2014 | 2013 | 2012 |
|---|---|---|---|
| Provision (Benefit) for Income Taxes | $(253) | $716 | $1,244 |

The provision for income taxes decreased from fiscal 2013 to fiscal 2014, primarily due to us recording tax benefits of $1.4 million during the fourth quarter of 2014 principally generated from our Swiss operations. These benefits were recorded after finalizing ongoing discussions with the Swiss tax authorities, or the STA, in connection with the completion of the Company's manufacturing consolidation project, which had been in progress since 2012 and completed in June 2014. These discussions included, among other things, the approval of a special Swiss tax ruling available to certain qualified companies doing business in Switzerland as a foreign operator, as defined by the STA. These discussions also included an agreement with the STA to consolidate the financial results of a foreign entity solely for Swiss income tax purposes, previously not taxable by the STA, to become subject to Swiss tax law. During the fourth quarter of 2014, we were advised by the STA that we had met their qualifications for 2014. This ruling will reduce our Swiss effective income tax rate commencing in 2015.

The provision for income taxes decreased from fiscal 2012 to fiscal 2013 primarily due to our release of the valuation allowance of our STAAR Japan subsidiary as of the third quarter ended September 27, 2013, which resulted in a tax benefit of $433,000 recognized during fiscal year 2013. We maintained a full valuation allowance for STAAR Japan in 2012.

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 9 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 option exercises, borrowings under lines of credit and by relying on equipment and other commercial financing. During 2014, 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.

We believe our current cash balances coupled with cash flow from operating activities will be sufficient to meet our working capital requirements for the foreseeable future, including the $4 million approximate cost in 2015 associated with our 2014 FDA Warning Letter and 2015 FDA-483 remediation efforts. Although we do anticipate these costs will continue into 2016, we cannot currently estimate the amount but will update as more information is available. Our 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 "*—Overview—Strategy*."

Our financial condition for each of the years indicated included the following (in millions):

| | 2014 | 2013 | 2012 | 2014 v. 2013 | 2013 v. 2012 |
|---|---|---|---|---|---|
| Cash and cash equivalents | $13.0 | $22.9 | $21.7 | $ (9.9) | $ 1.2 |
| Current assets | $44.9 | $50.1 | $44.1 | $ (5.2) | $ 6.0 |
| Current liabilities | 16.4 | 18.4 | 17.9 | (2.0) | 0.5 |
| Working capital | $28.5 | $31.7 | $26.2 | $ (3.2) | $ 5.5 |

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

Net cash used by operating activities was $8.0 million for fiscal year 2014 compared to cash provided by operating activities of $3.4 million, and $3.2 million for fiscal years 2013 and 2012, respectively. For 2014, net cash used in operating activities consisted of $8.4 million net loss, $6.2 million used for working capital and offset by non-cash operating activities of $6.7 million. For 2013, net cash provided by operating activities consisted of $0.4 million net

income, $7.4 million non-cash expenses and $4.4 million used for working capital. 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.

Net cash used in investing activities was $4.1 million, $3.4 million, and $2.1 million, for fiscal years 2014, 2013, and 2012, respectively, and relate primarily to the acquisition of property, plant and equipment. The increase in investment in property, plant and equipment during 2014, relative to 2013 was due to the investments made in connection with the relocation of all manufacturing to the Company's Monrovia, CA facility. The increase in investment in property, plant and equipment during 2013, relative to 2012, is due to investments made in connection with the Company's consolidation of its manufacturing operations to the U.S. In addition, during 2013, the Company made investments in leasehold improvements related to the expansion of the Company's Monrovia, CA facility.

Net cash provided by financing activities was $2.5 million, $2.4 million, and $4.3 million for fiscal years 2014, 2013, and 2012, respectively. For 2014, net cash provided by financial activities consisted of $0.5 million in repayment of capital lease obligations and $3.0 million of proceeds from exercise of stock options. For 2013, net cash provided by financial activities consisted of $0.8 million of repayment of capital lease lines of credit and $3.3 million in proceeds from exercise of stock options. 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.

Accounts receivable was $11.1 million as of January 2, 2015 and $10.7 million as of January 3, 2014  Days' Sales Outstanding ("DSO") was 54 days in 2014 and 55 days in 2013.

Inventories at the end of fiscal 2014 and 2013 were $15.7 million and $12.5 million, respectively. Days' inventory on hand ("DOH") was 155 days in 2014 and 159 days in 2013 for finished goods, including consignment inventory.

*Shelf Registration*

On February 26, 2014, STAAR filed a universal shelf registration statement with the SEC covering the future public offering and sale of up to $200 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 $4.2 million based on the rate of exchange on January 2, 2015), at an interest rate equal to the Tokyo short-term prime interest rate (approximately 1.475% as of January 2, 2015) and may be renewed annually (the current line expires on March 30, 2015). 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 2015. The Company had 500,000,000 Yen outstanding on the line of credit as of January 2, 2015 and January 3, 2014, (approximately $4.2 million and $4.8 million based on the foreign exchange rates on January 2, 2015 and January 3, 2014, respectively) which approximates fair value due to the short-term maturity and market interest rates of the line of credit. As of January 2, 2015, 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) ($1.0 million at the rate of exchange on January 2, 2015), 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 independent auditors' report, as defined. There were no borrowings outstanding as of January 2, 2015 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 January 2, 2015.

*Contractual Obligations*

The following table represents the Company's known contractual obligations as of January 2, 2015 (in thousands):

| | Payments Due by Period | | | | |
|---|---|---|---|---|---|
| Contractual Obligations | Total | 1 Year | **2-3 Years** | **4-5 Years** | **More Than 5 Years** |
| Line of credit | $4,150 | $4,150 | $— | $— | $— |
| Capital lease obligations | 934 | 442 | 492 | — | — |
| Operating lease obligations | 3,849 | 1,368 | 1,581 | 656 | 244 |
| Pension benefit payments | 1,607 | 135 | 310 | 228 | 934 |
| Severance | 180 | 40 | 140 | — | — |
| Open purchase orders | 472 | 472 | — | — | — |
| Total | $11,192 | $6,607 | $2,523 | $884 | $1,178 |

**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 significant 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 or 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 day 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.

We sell certain injector parts to an unrelated customer and supplier (collectively referred to as “supplier”) whereby these injector part sales are either made as a final sale to the supplier or, are sold to be reprocessed by the supplier into finished goods inventory (a preloaded acrylic IOL). These finished goods are then sold back to us at an agreed upon, contractual price. We make a profit margin on either type of sale with the supplier and each type of sale is made under separate purchase and sales orders between the two of us resulting in cash settlement for the orders sold or repurchased. For parts that are sold as a final sale, we recognize a sale consistent with its routine revenue recognition policies as disclosed above and those sales are included as part of other sales in total net sales. For the injector parts that are sold to be reprocessed into finished goods, we do not recognize revenue on these sales in accordance with Accounting Standards Codification (“ASC”) 845-10, *Purchases and Sales of Inventory with the Same Counterparty.* Instead, we record the transaction at its carrying value, deferring any profit margin in inventory, until the finished goods inventory is sold to an end-customer (not the supplier) at which point we record the sale and the

related cost of sale, including the release of the deferred cost of sale in inventory, related to these finished goods.

For all sales, we are the principal in the transaction as we, among other factors, are the primary obligor in the arrangement, 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 consolidated 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 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, expected volatility of our stock and expected dividend yield. The amounts recorded in the financial statements for share-based compensation could vary significantly if we were to use different assumptions. We also issue restricted stock units, or RSUs, to certain executives which contain both a performance and a service condition such that they vest if the internally established revenue target is met or exceeded and the grantee is still employed with us on the measurement date, which is typically one year after the grant date. We recognize compensation cost for the RSUs if and when it is probable that the performance condition will be achieved, net of an estimate of pre-vesting forfeitures, over the requisite service period based on the grant-date fair value of the stock. We reassess the probability of vesting at each reporting period and adjust compensation cost based on our probability assessment.

*Income Taxes.* We account for income taxes, on a jurisdiction-by-jurisdiction basis, 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 in the jurisdictions in which they arise. 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 in the U.S. 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, we are regularly audited by federal, state and foreign tax authorities, and subject to periodic inquiries from those tax authorities regarding the amount of taxes due. These inquiries 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 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, certain acquired rights, developed technologies and customer relationships. We capitalize the cost of acquiring patents and licenses. We acquired certain customer relationships, acquired rights 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, which is our best estimate of the pattern of the economic benefits, which are based on legal, contractual and other provisions, and range from 10 to 21 years for patents, certain acquired rights 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. We determined 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 ASC 715, 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 ASC 715 on December 29, 2007, the date of the acquisition. STAAR Japan is not required, and we do not intend to provide any future contributions to this pension plan to meet benefit obligations and will therefore not have any plan assets. Benefit payments are made to beneficiaries from operating cash flows as they become due.

*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. Assumptions of expected asset returns and market-related values of plan assets are applicable to the Swiss Plan only. 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. As more manufacturing has shifted from Japan to the U.S. there will be increased foreign currency exposure to the Japanese yen. We do not currently hedge transactions to offset changes in foreign currency.

**Inflation**

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

**Recent Accounting Pronouncements**

See "*Part II. Item 8. "Financial Statements and Supplementary Data – Note 1 – Organization and Description of Business and Accounting Policies – Recent Accounting Pronouncements*" of this Annual Report on Form 10-K.

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 January 2, 2015, STAAR had $4.2 million of foreign debt. Our $4.2 million of foreign debt bears an interest rate that is equal to the Tokyo short-term prime interest rate (approximately 1.475% as of January 2, 2015). 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 $42,000.

*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.

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

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

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. The report of BDO USA, LLP, our independent registered public accounting firm, regarding its audit of STAAR's internal control over financial reporting follows below. 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 January 2, 2015, 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.

**Changes in Internal Control over Financial Reporting**

There was no change during the fiscal quarter ended January 2, 2015 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

**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 January 2, 2015, based on the criteria for effective internal control described in Internal Control — Integrated Framework (2013) 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 January 2, 2015.

**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 January 2, 2015, based on criteria established in Internal Control – Integrated Framework (2013) 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 January 2, 2015, 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 January 2, 2015 and January 3, 2014, 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 January 2, 2015 and our report dated March 13, 2015 expressed an unqualified opinion thereon.

/s/ BDO USA, LLP

Costa Mesa, California

March 13, 2015

Item 9B. Other Information

*Compensatory Arrangements of Certain Officers*:

The Compensation Committee engaged the Radford group as its compensation consultant to evaluate our compensation structure. On March 6, 2015, as part of the annual executive performance review process, our Compensation Committee recommended, and the Board of Directors awarded, the following 2015 salaries and bonus targets of certain executives: Stephen Brown, Vice President and Chief Financial Officer, 2015 salary of $314,150, and bonus target of 45%, Samuel Gesten, Vice President and General Counsel, 2015 salary of $332,690, and bonus target of 45%, Robin Hughes, Vice President, Research & Development and Clinical, 2015 salary of $334,750, and bonus target of 40%, and James Francese, Vice President, Marketing, 2015 salary of $276,040, and bonus target of 40%. The Board of Directors did not change Ms. Mason's compensation, which is set forth in the Employment

Agreement attached as an exhibit to a Form 8-K filed with the Commission on March 3, 2015.

**PART III**

Item 10. Directors, 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 for the 2015 annual meeting of stockholders (the "Proxy Statement") to be filed with the Securities and Exchange Commission within 120 days of the close of the fiscal year ended January 2, 2015.

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



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) |
| 10.1 | Indenture of Lease dated September 1, 1993, by and between the Company and FKT Associates and First through Third Additions Thereto.(6) |
| 10.2 | Second Amendment to Indenture of Lease dated September 21, 1998, between the Company and FKT Associates.(6) |
| 10.3 | Third Amendment to Indenture of Lease dated October 13, 2003, by and between the Company and FKT Associates.(7) |
| 10.4 | Fourth Amendment to Indenture of Lease dated September 30, 2006, by and between the Company and FKT Associates.(1) |
| 10.5 | 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) |
| 10.6 | 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) |
| 10.7 | |

| | |
|---|---|
| | 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) |
| 10.8 | Amendment No. 1 to Standard Industrial/Commercial Multi-Tenant Lease dated January 3, 2003, by and between the Company and California Rosen LLC.(7) |
| 10.9 | Lease Agreement dated July 12, 1994, between STAAR Surgical AG and Calderari and Schwab AG/SA.(9) |
| 10.10 | 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) |
| 10.11 | 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) |
| †10.12 | Form of Indemnification Agreement between the Company and certain officers and directors.(9) |
| 10.13 | Standard Industrial/Commercial Multi Tenant Lease — Gross dated October 6, 2005, entered into between the Company and Z & M LLC.(11) |
| 10.14 | Warrant Agreement between STAAR Surgical Company and Broadwood Partners, L.P., dated December 14, 2007.(12) |
| †10.15 | Amended and Restated Executive Employment Agreement by and between the Company and Barry G. Caldwell, dated December 31, 2008.(13) |
| †10.16 | Employment Agreement effective November 22, 2002 by and between the Company and Deborah Andrews.(14) |
| †10.17 | Letter of the Company dated April 11, 2007 to Deborah Andrews, Vice President and Chief Financial Officer, regarding compensation.(14) |

| | |
|---|---|
| 10.18 | Credit Agreement between STAAR Japan Inc. and Mizuho Bank Inc., dated October 31, 2007.(15) |
| 10.19 | Amended Credit Agreement between STAAR Japan Inc. and Mizuho Bank Ltd., dated June 30, 2009.(15) |
| 10.20 | Basic Agreement on Unsterilized Intraocular Lens Sales Transactions between Canon Staar Co., Inc. and Nidek Co., Ltd., dated May 23, 2005.(16) |
| 10.21 | Basic Agreement on Injector Product Sales Transactions between Canon Staar Co., Inc. and Nidek Co., Ltd., dated May 23, 2005.(16) |
| 10.22 | Memorandum of Understanding Concerning Basic Agreements for Purchase and Sale between STAAR Japan Inc. and Nidek Co., Ltd., dated December 25, 2008.(16) |
| 10.23 | Acrylic Preset supply Warranty Agreement between STAAR Japan Inc. and Nidek Co., Ltd., dated December 25, 2008.(16) |
| 10.24 | Framework Agreement for Loans between Credit Suisse and STAAR Surgical AG, dated August 12, 2010. (17) |
| †10.25 | Form of Executive Severance Agreement.(18) |
| †10.26 | Form of Executive Change In Control Agreement.(18) |
| 10.27 | Standard Industrial/Commercial Single – Tenant Lease – Net dated August 17 , 2012, by and between the Company and Pacific Equity Partners, LLC.(19) |
| †10.28 | Letter of the Company dated March 27, 2012 to Samuel Gesten, Vice President and General Counsel, regarding compensation.(21) |
| †10.29 | Letter of the Company dated August 10, 2012 to James Francese, Vice President, Global Marketing, regarding compensation. (21) |
| 10.30 | Amended Credit Agreement between STAAR Japan Inc. and Mizuho Bank Ltd., dated December 28, 2012. (21) |
| †10.31 | Amendment No. 2 to Amended and Restated Executive Employment Agreement by and between the Company and Barry G. Caldwell, dated December 7, 2012. (21) |
| †10.32 | Letter of the Company dated May 8, 2007 to Robin S. Hughes, Vice President of Marketing, regarding compensation. (21) |
| †10.33 | Letter of the Company dated August 7, 2013 to Stephen Brown, Vice President of Finance, and Chief Financial Officer, regarding compensation.(20) |
| 10.34 | **Amendment Agreement between STAAR Surgical AG and Nidek Co., Ltd., dated April 11, 2014.(23) |
| 10.35 | Separation Agreement and General Release by and between the Company and Barry G. Caldwell, dated October 1, 2014 (10) |
| †10.36 | Employment Agreement effective March 1, 2015 by and between the Company and Caren Mason, dated March 1, 2015. (22) |
| 14.1 | Code of Business Conduct and Ethics.(9) |
| 21.1 | List of 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.* |

101.INS XBRL Instance Document.*

101.SCH XBRL Taxonomy Schema.*

101.CAL XBRL Taxonomy Extension Calculation Linkbase.*

101.DEF XBRL Taxonomy Extension Definition Linkbase.*

101.LAB XBRL Taxonomy Extension Label Linkbase.*

101.PRE XBRL Taxonomy Extension Presentation Linkbase.*

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* Filed herewith.

** Portions of this exhibit were omitted pursuant to an order granting confidential treatment dated August 25, 2014.

† 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 Current Report on Form 8-K as filed on June 11, 2014.

(2) Incorporated by reference to the Company's Current Report on Form 8-K as filed on June 11, 2014.

(3) Incorporated by reference to the Company's Proxy Statement for its Annual Meeting of Stockholders held on May 29, 1998, as 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 Quarterly Report on Form 10-Q for the period ended July 4, 2014, as filed on July 31, 2014.

(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 to 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 to 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 8K as filed on October 7, 2014.
(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 as filed on December 17, 2007.
(13) Incorporated by reference to the Company's Current Report on Form 8-K as filed on January 8, 2009.
(14) Incorporated by reference to the Company's Current Report on Form 8-K as filed on October 1, 2009.
(15) 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.
(16) Incorporated by reference to the Company's Annual Report on Form 10-K for the year ended January 1, 2010 as filed on March 11, 2011.
(17) 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.
(18) 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.
(19) Incorporated by reference to the Company's Current Report on Form 8-K as filed on August 23, 2012.
(20) Incorporated by reference to the Company's Current Report on Form 8-K as filed on September 9, 2013.
(21) Incorporated by reference to the Company's Annual Report on Form 10-K for the year ended December 28, 2012, as filed on March 12, 2013.
(22) Incorporated by reference to the Company's Current Report on Form 8-K as filed on March 3, 2015.
(23) Incorporated by reference to the Company's Quarterly Report on Form 10-Q for the period ended April 4, 2014, as filed on May 13, 2014.

**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 13, 2015 By: /s/ Caren Mason
Caren Mason
*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/ Caren Mason<br>Caren Mason | President, Chief Executive Officer and Director (principal executive officer) | March 13, 2015 |
| /s/ Stephen P. Brown<br>Stephen P. Brown | Vice President, Chief Financial Officer (principal accounting and financial officer) | March 13, 2015 |
| /s/ Mark B. Logan<br>Mark B. Logan | Chairman of the Board, Director | March 13, 2015 |
| /s/ Richard A. Meier<br>Richard A. Meier | Director | March 13, 2015 |
| /s/ John C. Moore<br>John C. Moore | Director | March 13, 2015 |
| /s/ Louis E. Silverman<br>Louis E. Silverman | Director | March 13, 2015 |
| /s/ Charles Slacik<br>Charles Slacik | Director | March 13, 2015 |

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**STAAR SURGICAL COMPANY AND SUBSIDIARIES**

**CONSOLIDATED FINANCIAL STATEMENTS**

**Years Ended January 2, 2015, January 3, 2014, and December 28, 2012**

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**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 January 2, 2015 and January 3, 2014 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 January 2, 2015. In connection with our audits of the consolidated financial statements, we have also audited the consolidated financial schedule listed in Item 15. These financial statements and schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements and schedule 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 presentation of the financial statements and schedule. 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 January 2, 2015 and January 3, 2014, and the results of their operations and their cash flows for each of the three years in the period ended January 2, 2015, in conformity with accounting principles generally accepted in the United States of America.

Also in our opinion, the consolidated financial statement schedule, when considered in relation to the basic consolidated financial statements taken as a whole, presents fairly, in all material respects, the information set forth therein.

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 January 2, 2015, based on criteria established in *Internal Control – Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) and our report dated March 13, 2015 expressed an

unqualified opinion thereon.

/s/ BDO USA, LLP

Costa Mesa, California

March 13, 2015

**STAAR SURGICAL COMPANY AND SUBSIDIARIES**

**CONSOLIDATED BALANCE SHEETS**

**January 2, 2015 and January 3, 2014**

| | 2014 | 2013 |
|---|---|---|
| | (In thousands, except par value amounts) | |
| ASSETS | | |
| Current assets: | | |
| Cash and cash equivalents | $13,013 | $22,954 |
| Accounts receivable trade, net | 11,054 | 10,731 |
| Inventories, net | 15,717 | 12,514 |
| Prepaids, deposits and other current assets | 4,517 | 3,503 |
| Deferred income taxes | 596 | 373 |
| Total current assets | 44,897 | 50,075 |
| Property, plant and equipment, net | 10,066 | 7,405 |
| Intangible assets, net | 870 | 1,380 |
| Goodwill | 1,786 | 1,786 |
| Deferred income taxes | 695 | 626 |
| Other assets | 597 | 659 |
| Total assets | $58,911 | $61,931 |
| | | |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | |
| Current liabilities: | | |
| Line of credit | $4,150 | $4,750 |
| Accounts payable | 6,620 | 6,263 |
| Deferred income taxes | 301 | 739 |
| Obligations under capital leases | 399 | 288 |
| Other current liabilities | 4,976 | 6,372 |
| Total current liabilities | 16,446 | 18,412 |
| Obligations under capital leases | 468 | 141 |
| Deferred income taxes | 1,704 | 1,654 |
| Asset retirement obligations | 115 | 157 |
| Pension liability | 3,079 | 2,715 |
| Total liabilities | 21,812 | 23,079 |
| Commitments and contingencies (Note 12) | | |
| Stockholders' equity: | | |
| Common stock, $0.01 par value; 60,000 shares authorized: 38,429 and 37,911 shares issued and outstanding at January 2, 2015 and January 3, 2014, respectively | 384 | 379 |
| Additional paid-in capital | 178,232 | 170,246 |
| Accumulated other comprehensive income (loss) | (1,070) | 282 |

| | | |
|---|---|---|
| Accumulated deficit | (140,447) | (132,055) |
| Total stockholders' equity | 37,099 | 38,852 |
| Total liabilities and stockholders' equity | $58,911 | $61,931 |

*The accompanying notes are an integral part of these consolidated financial statements.*

**STAAR SURGICAL COMPANY AND SUBSIDIARIES**

**CONSOLIDATED STATEMENTS OF OPERATIONS**

**Years Ended January 2, 2015, January 3, 2014, and December 28, 2012**

| | 2014 | 2013 | 2012 |
|---|---|---|---|
| | (In thousands, except per share amounts) | | |
| Net sales | $74,987 | $72,215 | $63,783 |
| Cost of sales | 26,164 | 21,906 | 19,492 |
| Gross profit | 48,823 | 50,309 | 44,291 |
| Selling, general and administrative expenses: | | | |
| General and administrative | 18,160 | 16,568 | 15,150 |
| Marketing and selling | 25,879 | 23,888 | 21,281 |
| Research and development | 12,363 | 6,708 | 6,444 |
| Medical device excise tax | 127 | 203 | — |
| Other general and administrative expenses | 321 | 2,242 | 2,636 |
| Operating income (loss) | (8,027) | 700 | (1,220) |
| Other income (expense): | | | |
| Interest income | 51 | 59 | 59 |
| Interest expense | (154) | (170) | (291) |
| Gain (loss) on foreign currency transactions | (896) | 39 | 111 |
| Other income, net | 381 | 486 | 822 |
| Other income (expense), net | (618) | 414 | 701 |
| Income (loss) before provision (benefit) for income taxes | (8,645) | 1,114 | (519) |
| Provision (benefit) for income taxes | (253) | 716 | 1,244 |
| Net income (loss) | $(8,392) | $398 | $(1,763) |
| | | | |
| Net income (loss) per share – basic | $(0.22) | $0.01 | $(0.05) |
| Net income (loss) per share – diluted | $(0.22) | $0.01 | $(0.05) |
| | | | |
| Weighted average shares outstanding – basic | 38,091 | 36,706 | 36,253 |
| Weighted average shares outstanding – diluted | 38,091 | 38,607 | 36,253 |

*The accompanying notes are an integral part of these consolidated financial statements.*

**STAAR SURGICAL COMPANY AND SUBSIDIARIES**

**CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)**

**Years Ended January 2, 2015, January 3, 2014, and December 28, 2012**

| | 2014 | 2013 | 2012 |
|---|---|---|---|
| | (In thousands) | | |
| Net income (loss) | $(8,392) | $398 | $(1,763) |
| Other comprehensive income (loss), net of tax: | | | |
| Foreign currency translation adjustment, net of tax | (955) | (1,327) | (689) |
| Pension liability adjustment, net of tax | (397) | 29 | (136) |
| Other comprehensive loss | (1,352) | (1,298) | (825) |
| Comprehensive loss | $(9,744) | $(900) | $(2,588) |

*The accompanying notes are an integral part of these consolidated financial statements.*

**STAAR SURGICAL COMPANY AND SUBSIDIARIES**

**CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY**

**Years Ended January 2, 2015, January 3, 2014, and December 28, 2012**

(**In thousands**)

| | Common Stock Shares | Common Stock Par Value | Additional Paid-In Capital | Accumulated Other Comprehensive Income (AOCI) | Retained Earnings (Accumulated Deficit) | Total |
|---|---|---|---|---|---|---|
| Balance, at December 30, 2011 | 36,041 | $ 361 | $ 157,382 | $ 2,405 | $ (130,690) | $ 29,458 |
| Net loss | — | — | — | — | (1,763) | (1,763) |
| Other comprehensive loss | — | — | — | (825) | — | (825) |
| Common stock issued upon exercise of options | 324 | 3 | 1,511 | — | — | 1,514 |
| Stock-based compensation | — | — | 3,358 | — | — | 3,358 |
| Vested restricted stock | 58 | — | — | — | — | — |
| Balance, at December 28, 2012 | 36,423 | 364 | 162,251 | 1,580 | (132,453) | 31,742 |
| Net income | — | — | — | — | 398 | 398 |
| Other comprehensive loss | — | — | — | (1,298) | — | (1,298) |
| Common stock issued upon exercise of options | 645 | 7 | 3,279 | — | — | 3,286 |
| Common stock issued upon cashless exercise of warrants | 485 | 5 | (5) | — | — | — |
| Stock-based compensation | — | — | 4,721 | — | — | 4,721 |
| Unvested restricted stock | 341 | 3 | — | — | — | 3 |
| Vested restricted stock | 17 | — | — | — | — | — |
| Balance, at January 3, 2014 | 37,911 | 379 | 170,246 | 282 | (132,055) | 38,852 |
| Net loss | — | — | — | — | (8,392) | (8,392) |
| Other comprehensive loss | — | — | — | (1,352) | — | (1,352) |
| Common stock issued upon exercise of options | 457 | 4 | 3,018 | — | — | 3,022 |
| Common stock issued upon cashless exercise of options | 127 | 1 | (1) | — | — | — |
| Stock-based compensation | — | — | 4,969 | — | — | 4,969 |
| Unvested restricted stock | (341) | (3) | — | — | — | (3) |
| Vested restricted stock | 275 | 3 | — | — | — | 3 |
| Balance, at January 2, 2015 | 38,429 | $ 384 | $ 178,232 | $ (1,070) | $ (140,447) | $ 37,099 |

*The accompanying notes are an integral part of these consolidated financial statements*

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**STAAR SURGICAL COMPANY AND SUBSIDIARIES**

**CONSOLIDATED STATEMENTS OF CASH FLOWS**

**Years Ended January 2, 2015, January 3, 2014, and December 28, 2012**

| | 2014 | 2013 | 2012 |
|---|---|---|---|
| | (In thousands) | | |
| Cash flows from operating activities: | | | |
| Net income (loss) | $(8,392) | $398 | $(1,763) |
| Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities: | | | |
| Depreciation of property and equipment | 2,078 | 1,711 | 1,309 |
| Amortization of intangibles | 382 | 440 | 652 |
| Deferred income taxes | (841) | 104 | 143 |
| Fair value adjustment of warrant | — | (27) | (335) |
| Change in net pension liability | 194 | 162 | 205 |
| Loss on disposal of property and equipment | — | 200 | 131 |
| Stock-based compensation expense | 4,663 | 4,489 | 3,208 |
| Accretion of asset retirement obligation | 3 | 10 | 16 |
| Provision for sales returns and bad debts | 182 | 263 | 77 |
| Changes in working capital: | | | |
| Accounts receivable trade, net | (934) | (2,938) | 224 |
| Inventories, net | (3,943) | (1,603) | (1,020) |
| Prepaids, deposits and other current assets | (1,062) | (1,063) | (298) |
| Accounts payable | 972 | 367 | 1,014 |
| Other current liabilities | (1,253) | 842 | (346) |
| Net cash provided by (used in) by operating activities | (7,951) | 3,355 | 3, 217 |
| Cash flows from investing activities: | | | |
| Acquisition of property and equipment | (4,054) | (3,448) | (2,271) |
| Net change in other noncurrent assets | — | — | (4) |
| Decrease in restricted cash, including reinvested interest | — | — | 129 |
| Net cash used in investing activities | (4,054) | (3,448) | (2,146) |
| Cash flows from financing activities: | | | |
| Borrowings under lines of credit | — | — | 3,510 |
| Repayment of capital lease lines of credit | (490) | (841) | (741) |
| Proceeds from the exercise of stock options | 3,022 | 3,286 | 1,514 |
| Net cash provided by financing activities | 2,532 | 2,445 | 4,283 |
| Effect of exchange rate changes on cash and cash equivalents | (468) | (1,073) | (261) |
| Increase (decrease) in cash and cash equivalents | (9,941) | 1,279 | 5,093 |
| Cash and cash equivalents, at beginning of year | 22,954 | 21,675 | 16,582 |
| Cash and cash equivalents, at end of year | $13,013 | $22,954 | $21,675 |

*The accompanying notes are an integral part of these consolidated financial statements*

**STAAR SURGICAL COMPANY AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**Note 1 — Organization and Description of Business and Accounting Policies**

***Organization and Description of Business***

STAAR Surgical Company and subsidiaries (the "Company"), a Delaware corporation, was incorporated in 1982 for the purpose of developing, producing, and marketing intraocular lenses ("IOLs") and other products for minimally invasive ophthalmic surgery. Principal products are IOLs and implantable Collamer lenses ("ICLs"). IOLs are prosthetic intraocular lenses used to restore vision that has been adversely affected by cataracts, and include the Company's lines of silicone and Collamer IOLs and the Preloaded Injector (a silicone or acrylic IOL preloaded into a single-use disposable injector). ICLs, consisting of the Company's ICL and Toric implantable collamer lenses ("TICL"), are intraocular lenses used to correct refractive conditions such as myopia (near-sightedness), hyperopia (far-sightedness) and astigmatism.

As of January 2, 2015, the Company's significant subsidiaries consisted of:

- STAAR Surgical AG, a wholly owned subsidiary formed in Switzerland that markets and distributes ICLs and Preloaded IOLs.
- STAAR Japan, a wholly owned subsidiary that markets and distributes Preloaded IOLs and ICLs.
- STAAR Surgical Cayman, Inc., a wholly owned subsidiary formed to develop, maintain, and own intellectual property underlying the Company's products marketed, distributed, and sold worldwide, excluding the Americas.

The Company operates as one operating segment, the ophthalmic surgical market, for financial reporting purposes (see Note 16).

***Principles of Consolidation***

The accompanying consolidated financial statements include the accounts of STAAR Surgical and its wholly-owned subsidiaries and have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP"). All significant intercompany balances and transactions have been eliminated.

***Fiscal Year and Interim Reporting Periods***

The Company's fiscal year ends on the Friday nearest December 31 and each of the Company's quarterly reporting periods generally consists of 13 weeks. Fiscal year 2014 is based on a 52-week period, fiscal year 2013 is based on a 53-week period, and fiscal year 2012 is based on a 52-week period.

***Foreign Currency***

The functional currency of the Company's Japanese subsidiary is the Japanese yen. The functional currency of the Company's Swiss subsidiary, STAAR Surgical AG, is the U.S. dollar.

Assets and liabilities of the Company's Japanese subsidiary are translated at rates of exchange in effect at the close of the period. Sales and expenses are translated at the weighted average of exchange rates in effect during the period. The resulting translation gains and losses are deferred and are shown as a separate component in the Consolidated Statement of Comprehensive Income (Loss). During 2014, 2013, and 2012, the net foreign translation losses were $955,000, $1,327,000, and $689,000, respectively, and net foreign currency transaction gains (losses), included in the consolidated statements of operations under other income (expense) were, (896,000), $39,000, and $111,000, respectively.

***Revenue Recognition***

The Company recognizes revenue when realized or realizable and earned, which is when the following criteria are met: persuasive evidence of an arrangement exists; delivery has occurred; the sale price is fixed or 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 the STAAR Japan subsidiary, which is typically recognized when the product is received by the customer. STAAR Japan does not have significant deferred revenues as of January 2, 2015 as delivery to the customer is generally made within the same or the next day of shipment. The Company presents sales tax it collects from its customers on a net basis (excluded from revenues).

**STAAR SURGICAL COMPANY AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

The Company's products are marketed to ophthalmic surgeons, hospitals, ambulatory surgery centers or vision centers, and distributors. IOLs may be offered to surgeons and hospitals on a consignment basis. The Company maintains title and risk of loss of consigned inventory and recognizes revenue for consignment inventory when the Company is notified that the IOL has been implanted.

ICLs are sold only to certified surgeons who have completed requisite training or for use in scheduled training surgeries. As a result, STAAR partially mitigates the risk that the revenue it recognizes on shipment of ICLs would need to be reversed because of a surgeon's failure to qualify for its use.

The Company sells certain injector parts to an unrelated customer and supplier (collectively referred to as "supplier") whereby these injector part sales are either made as a final sale to the supplier or, are sold to be reprocessed by the supplier into finished goods inventory (a preloaded acrylic IOL). These finished goods are then sold back to the Company at an agreed upon, contractual price. The Company makes a profit margin on either type of sale with the supplier and each type of sale is made under separate purchase and sales orders between the two parties resulting in cash settlement for the orders sold or repurchased. For parts that are sold as a final sale, the Company recognizes a sale consistent with its routine revenue recognition policies as disclosed above and those sales are included as part of other sales in total net sales. For the injector parts that are sold to be reprocessed into finished goods, the Company does not recognize revenue on these sales in accordance with ASC 845-10, *Purchases and Sales of Inventory with the Same Counterparty*. Instead, the Company records the transaction at its carrying value, deferring any profit margin as contra-inventory, until the finished goods inventory is sold to an end-customer (not the supplier) at which point the Company records the sale and the related cost of sale, including the release of the deferred cost of sale in inventory, related to these finished goods.

For all sales, the Company is considered the principal in the transaction as the Company, among other factors, is the primary obligor in the arrangement, bears general inventory risk, credit risk, has latitude in establishing the sales price, is responsible for authorized and general sales returns risk and therefore, sales and cost of sales are reported separately in the consolidated 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.

The Company generally permits returns of product if the product is returned within the time allowed by its return policies and records an allowance for estimated returns at the time revenue is recognized. The Company's allowance for estimated returns considers historical trends and experience, the impact of new product launches, the entry of a

competitor, availability of timely and pertinent information and the various terms and arrangements offered, including sales with extended credit terms. Sales are reported net of estimated returns.

The Company performs ongoing credit evaluations of its customers and adjusts credit limits based on customer payment history and credit worthiness, as determined by the Company's review of its customers' current credit information. The Company continuously monitors collections and payments from customers and maintains a provision for estimated credit losses and uncollectible accounts based upon its historical experience and any specific customer collection issues that have been identified. Amounts determined to be uncollectible are written off against the allowance for doubtful accounts.

***Use of Estimates***

The consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America and, as such, include amounts based on significant estimates and judgments of management with consideration given to materiality. Significant estimates used include determining valuation allowances for uncollectible trade receivables, sales returns reserves, obsolete and excess inventory, deferred income taxes, and tax reserves, including valuation allowances for deferred tax assets, pension liabilities, evaluation of asset impairment, in determining the useful life of depreciable and definite-lived intangible assets, and in the variables and assumptions used to calculate and record stock-based compensation. Actual results could differ materially from those estimates.

**STAAR SURGICAL COMPANY AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

***Cash and Cash Equivalents***

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

***Concentration of Credit Risk and Revenues***

Financial instruments that potentially subject the Company to credit risk principally consist of trade receivables. This risk is limited due to the large number of customers comprising the Company's customer base, and their geographic dispersion. As of January 2, 2015, there were two customers with trade receivables balances that represented 10% or more of consolidated trade receivables. As of January 3, 2014, there were no customers with trade receivables balances that represented 10% or more of consolidated trade receivable. Ongoing credit evaluations of customers' financial condition are performed and, generally, no collateral is required. The Company maintains reserves for potential credit losses and such losses, in the aggregate, have not exceeded management's expectations.

A single customer has accounted for 11% of the Company's consolidated net sales in fiscal 2013 and 2012 and 9% in 2014.

***Fair Value of Financial Instruments***

Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. To increase the comparability of fair value measures, the following hierarchy prioritizes the inputs to valuation methodologies used to measure fair value (Accounting Standards Codification ("ASC") 820-10):

- Level 1 – Inputs to the valuation methodology are quoted prices (unadjusted) for identical assets or liabilities in active markets.

- Level 2 – Inputs to the valuation methodology include quoted prices for similar assets or liabilities in active markets, and inputs that are observable for the assets or liability, either directly or indirectly, for substantially the full term of the financial instruments.

- Level 3 – Inputs to the valuation methodology are unobservable; that reflect management's own assumptions about the assumptions market participants would make and significant to the fair value.

The carrying values reflected in the consolidated balance sheets for cash and cash equivalents, trade accounts receivable, prepaids and other current assets, accounts payable, other current liabilities and line of credit approximate their fair values because of the short maturity of these instruments.

***Inventories, Net***

Inventories, net are valued at the lower of cost, determined on a first-in, first-out basis, or market. Inventories include the costs of raw material, labor, and manufacturing overhead, work in process and finished goods. Inventories also include deferred margins for certain injector parts described under the revenue recognition policy. The Company provides estimated inventory allowances for excess, expiring, slow moving and obsolete inventory as well as inventory whose carrying value is in excess of net realizable value to properly reflect inventory at the lower of cost or market.

***Property, Plant and Equipment***

Property, plant and equipment are recorded at cost. Depreciation on property, plant, and equipment is computed using the straight-line method over the estimated useful lives of the assets as noted below. Leasehold improvements are amortized over the lesser of the estimated useful lives of the assets or the related lease term. Major improvements are capitalized and minor replacements, maintenance and repairs are charged to expense as incurred.

**STAAR SURGICAL COMPANY AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

The estimated useful lives of assets are as follows:

| | |
|---|---|
| Machinery and equipment | 5-10 years |
| Furniture and equipment | 3-7 years |
| Computer and peripherals | 2-5 years |
| Leasehold improvements | (a) |

(a) The estimated useful life of leasehold improvements are the shorter of the useful life of the asset or the term of the associated leases.

***Goodwill***

Goodwill, which has an indefinite life, is not amortized but instead is tested for impairment on an annual basis or between annual tests if an event occurs or circumstances change that would indicate the carrying amount may be impaired. Impairment testing for goodwill is done at the reporting unit level. Reporting units can be one level below the operating segment level, and can be combined when reporting units within the same operating segment have similar economic characteristics. The Company has determined that its reporting units have similar economic characteristics, and therefore, can be combined into one reporting unit for the purposes of goodwill impairment testing. During the fourth quarter of fiscal 2014 and 2013, the Company performed its annual impairment test and determined that its goodwill was not impaired. As of January 2, 2015 and January 3, 2014, the carrying value of goodwill was $1.8 million.

***Long-Lived Assets***

The Company reviews property and equipment and intangible assets, excluding goodwill, for impairment whenever events or changes in circumstances indicate the carrying amount of an asset may not be recoverable. The Company measures recoverability of these assets by comparing the carrying value of such assets to the estimated undiscounted future cash flows the assets are expected to generate. When the estimated undiscounted future cash flows are less than their carrying amount, an impairment loss is recognized equal to the difference between the assets' fair value and their

carrying value. A review of long lived assets was conducted as of January 2, 2015 and January 3, 2014 and no impairment was identified.

Amortization is computed on the straight-line basis, which is the Company's best estimate of the economic benefits realized over the estimated useful lives of the assets which range from 3 to 20 years for patents, certain acquired rights and licenses, 10 years for customer relationships, and 3 to 10 years for developed technology.

***Research and Development Costs***

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

***Advertising Cost***

Advertising costs, which are included in marketing and selling expenses, are expensed as incurred. Advertising costs were $2.8 million, $2.1 million and $1.8 million for 2014, 2013 and 2012, respectively.

***Income Taxes***

The Company recognizes deferred tax assets and liabilities for temporary differences between the financial reporting basis and the tax basis of the Company's assets and liabilities, net operating loss and credit carryforwards, and uncertainty in income taxes, on a jurisdiction-by-jurisdiction basis. Valuation allowances, or reductions to deferred tax assets, are recognized if, based on the weight of available evidence, it is more likely than not that some portion or all of the deferred tax asset may not be realized or realizable in the jurisdiction in which they arise. The impact on deferred taxes of changes in tax rates and laws, if any, are applied to the years during which temporary differences are expected to be settled and reflected in the financial statements in the period of enactment.

**STAAR SURGICAL COMPANY AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

The Company recognizes the income tax benefit from an uncertain tax position when it is more likely than not that, based on technical merits, the position will be sustained upon examination, including resolutions of any related appeals or litigation processes. The amount of tax benefit recorded, if any, is limited to the amount that is greater than 50 percent likely to be realized upon settlement with the taxing authority (that has full knowledge of all relevant information). Accrued interest, if any, related to uncertain tax positions is included as a component of income tax expense, and penalties, if incurred, are recognized as a component of operating income or loss. The Company does not have any uncertain tax positions as of any of the periods presented. The Company did not incur significant interest and penalties for any period presented.

***Basic and Diluted Net Income (Loss) Per Share***

The Company has only one class of common stock and no participating securities which would require the two-class method of calculating basic earnings per share. Basic per share information is calculated by dividing net income (loss) by the weighted average number of shares outstanding, net of unvested restricted stock, during the period. Diluted per share information is calculated by dividing net income (loss) by the weighted average number of shares outstanding, adjusted for the effects of potentially dilutive common stock, which are comprised of outstanding warrants, stock options, unvested restricted stock and restricted stock units, during the period, using the treasury-stock method.

***Employee Defined Benefit Plans***

The Company maintains a passive pension plan (the “Swiss Plan”) covering employees of its Swiss subsidiary. The Swiss Plan conforms to the features of a defined benefit plan.

The Company also maintains a noncontributory defined benefit pension plan which covers substantially all of the employees of STAAR Japan.

The Company recognizes 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 (loss). If the projected benefit obligation exceeds the fair value of plan assets, then that difference or unfunded status represents the pension liability. The Company records 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 (asset returns and fair-value of plan assets are applicable for the Swiss Plan only). The fair values of plan assets are determined based on prevailing market prices (see Note 10).

***Stock Based Compensation***

Stock-based compensation expense for all stock-based compensation awards granted is based on the grant-date fair value. The Company recognizes these compensation costs on a straight-line basis over the requisite service period of the award, which is generally the option vesting term of three to four years (see Note 11).

The Company also issues restricted stock to its executive officers and Board of Directors (the Board), which are restricted and unvested common shares issued at fair market value on the date of grant. For the restricted shares issued to the Board, the restricted stock vests over a one-year service period and are subject to forfeiture (or acceleration, depending upon the circumstances) until vested or the service period is completed. The Company has also issued performance accelerated restricted stock (PARS) to its executive officers which carry a three year service condition and a performance condition such that if the Company meets or exceeds certain predetermined performance metrics set by the Board, up to one third of the grant vesting may be accelerated annually. If the performance metrics are not achieved, the restricted stock vests after three years. Restricted stock compensation expense is recognized on a straight-line basis over the requisite service period of one to three years for the Board and PARS grants, respectively, based on the grant-date fair value of the stock. Restricted stock is considered legally issued and outstanding on the grant date (see Notes 11 and 15).

**STAAR SURGICAL COMPANY AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

The Company issues restricted stock units ("RSUs") under the 2013 RSU Plan (see Note 11), which is a performance contingent restricted stock award based upon the Company exceeding an internally established annual revenue target which is above the established annual revenue plan. The RSUs contain both a performance and a service condition such that they vest after calculating the total financial performance for fiscal year 2014, at which time, if the internally established revenue target is met or exceeded and the grantee is still employed with the Company on the measurement date, which is one year after the grant date, the RSUs will become fully vested. The Company recognizes compensation cost for the RSUs if and when the Company concludes that it is probable that the performance condition will be achieved, net of an estimate of pre-vesting forfeitures, over the requisite service period based on the grant-date fair value of the stock. The Company reassesses the probability of vesting at each reporting period and adjusts compensation cost based on its probability assessment.

Once the RSUs are vested, equivalent common shares will be issued or issuable to the grantee and therefore the RSUs are not included in total common shares issued and outstanding until vested (see Notes 11 and 15).

The Company accounts for options granted to persons other than employees and directors under *Equity –Based Payments to Non-Employees*. The fair value of such options is re-measured each reporting period using the Black-Scholes option-pricing model and income or expense is recognized over the vesting period for changes to the fair value for the unvested options. As the options vest, no such re-measurement is necessary or performed.

***Accounting for Warrants***

The Company has issued certain warrants under an agreement that expressly provides that if the Company fails to satisfy continuous registration requirements the Company will be obligated only to issue additional common stock as the holder's sole remedy, with no possibility of settlement in cash. The Company accounts for these warrants as equity because additional shares are the only form of settlement available to the holder. These warrants are only valued on the issuance date and not subsequently revalued. The Company uses the Black-Scholes option pricing model as the valuation model to estimate the fair value of all warrants. (See Note 11).

***Comprehensive Income (Loss)***

The Company presents comprehensive income (loss) in two separate but not consecutive consolidated financial statements, the Consolidated Statements of Operations and the Consolidated Statements of Comprehensive Income (Loss). Total comprehensive income (loss) includes, in addition to net income (loss), changes in equity that are excluded from the consolidated statements of operations and are recorded directly into a separate section of stockholders' equity on the consolidated balance sheets. The following table summarizes the changes in the accumulated balances for each component of accumulated other comprehensive income (loss) attributable to the Company for the years ended January 2, 2015, January 3, 2014, and December 28, 2012 (in thousands):

| | Foreign Currency Translation | Defined Benefit Pension Plan-Japan | Defined Benefit Pension Plan-Switzerland | Accumulated Other Comprehensive Income (Loss) |
|---|---|---|---|---|
| Balance, at December 30, 2011 | $ 2,795 | $ 423 | $ (813) | $ 2,405 |
| Other comprehensive loss | (689) | (127) | (11) | (827) |
| Tax effect | - | - | 2 | 2 |
| Balance, at December 28, 2012 | 2,106 | 296 | (822) | 1,580 |
| Other comprehensive income (loss) | (861) | (126) | 280 | (707) |
| Tax effect | (466) | (63) | (62) | (591) |
| Balance, at January 3, 2014 | 779 | 107 | (604) | 282 |
| Other comprehensive income (loss) | (1,527) | 23 | (359) | (1,863) |
| Tax effect | 572 | (9) | (52) | 511 |
| Balance, at January 2, 2015 | $ (176) | $ 121 | $ (1,015) | $ (1,070) |

**STAAR SURGICAL COMPANY AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

***Recent Accounting Pronouncements***

In August 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2014-15, "Presentation of Financial Statements Going Concern (Subtopic 205-40) – Disclosure of Uncertainties about and Entity's Ability to Continue as a Going Concern". Currently there is no guidance in GAAP about management's responsibility to evaluate whether there is substantial doubt about the entity's ability to continue as a going concern. This ASU requires management to assess the entity's ability to continue as a going concern. This guidance is effective for fiscal years ending after December 15, 2016. Early adoption is permitted. The Company expects to adopt this guidance when effective, and upon adoption, will evaluate going concern based on this guidance.

In June 2014, the FASB issued ASU 2014-12, "Compensation – Stock Compensation (Topic 718): Accounting for Shared Based Payments When the Terms of an Award Provide That a Performance Target Could Be Achieved After the Requisite Service Period (a consensus of the FASB Emerging Issues Task Force)". ASU 2014-12 is effective for fiscal years, and interim periods within those years, beginning after December 15, 2015. The Company is assessing the impact, if any, to the consolidated financial statements.

In May 2014, the FASB issued ASU 2014-09, "Revenue from Contracts with Customers (Topic 606)". This guidance includes the required steps to achieve the core principle that an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. This guidance is effective for fiscal years and interim periods beginning after December 15, 2016. Early adoption is not permitted. The Company expects to adopt this guidance when effective, and the impact on its consolidated financial statements is not currently estimable.

**Note 2 — Accounts Receivable Trade, Net**

Accounts receivable trade, net consisted of the following at January 2, 2015 and January 3, 2014 (in thousands):

| | 2014 | 2013 |
|---|---|---|

| | | |
|---|---|---|
| Domestic | $1,818 | $2,135 |
| Foreign | 10,825 | 10,045 |
| | 12,643 | 12,180 |
| Less allowance for doubtful accounts and sales returns | 1,589 | 1,449 |
| | $11,054 | $10,731 |

**Note 3 — Inventories, Net**

Inventories, net consisted of the following at January 2, 2015 and January 3, 2014 (in thousands):

| | 2014 | 2013 |
|---|---|---|
| Raw materials and purchased parts | $2,146 | $1,367 |
| Work in process | 1,781 | 913 |
| Finished goods | 14,504 | 11,029 |
| | 18,431 | 13,309 |
| Less inventory reserves | 2,714 | 795 |
| | $15,717 | $12,514 |

**STAAR SURGICAL COMPANY AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**Note 4 — Prepaids, Deposits, and Other Current Assets**

Prepaids, deposits, and other current assets consisted of the following at January 2, 2015 and January 3, 2014 (in thousands):

| | 2014 | 2013 |
|---|---|---|
| Prepaids and deposits | $1,991 | $2,157 |
| Income tax receivable | 1,084 | — |
| Value added tax (VAT) receivable | 721 | 618 |
| Deferred charge for foreign profits | | |