STAAR SURGICAL CO
Form 10-K
March 11, 2016

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K

(Mark One)

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

For the fiscal year ended January 1, 2016
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. ¨

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 o No þ

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant as of July 2, 2015, the last business day of the registrant's most recently completed second fiscal quarter, was approximately $365,994,000 based on the closing price per share of $9.36 of the registrant's Common Stock on that date.

The number of shares outstanding of the registrant's Common Stock as of February 26, 2016 was 40,159,827.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement relating to its 2016 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, and the Private Securities Litigation Reform Act of 1995, and is subject to the safe harbor created therein. 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," "intend," "plan," "believe," "will," "forecast" and similar expressions in connection with any discussion of future operating 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. We caution you not to place undue reliance on these forward-looking statements and to note they speak only as of the date hereof. Factors that could cause actual results to differ materially from those set forth in the forward-looking statements are included in the risk factors set forth in Item 1A, "Risk Factors." We disclaim any intention or obligation to update or revise any financial projections or forward-looking statements due to new information or other events.

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. Our goal is to position our refractive lenses throughout the world as primary and premium solutions for patients seeking visual freedom from wearing glasses or contact lenses while achieving excellent visual acuity through refractive vision correction. We also make lenses for use in surgery that treats cataracts.

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.

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 7.

Operations

STAAR has significant operations globally. Activities outside the United States ("U.S.") accounted for 86% of our total sales in fiscal year 2015, 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 U.S., Canada, Japan, Germany, the U.K. and Spain, and independent distribution in the remainder of the world.

STAAR maintains operational and administrative facilities in the U.S., Switzerland and Japan. Its current global operations are as follows:

- *United States.* STAAR operates its global administrative headquarters and principal manufacturing facility in Monrovia, California. The Monrovia manufacturing facility primarily makes the Visian implantable Collamer lenses (ICLs), Collamer and silicone intraocular lenses (IOLs), preloaded silicone IOLs, and injector systems. We manufacture the raw material for Collamer lenses (both IOLs and ICLs) and the AquaFlow Device (for the treatment of glaucoma) in our 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 performs final packaging of its silicone preloaded IOL injectors at the Ichikawa City facility.

Financial Information about Segments and Geographic Areas

100% of the Company's sales are generated from the ophthalmic surgical product segment and, therefore, the Company operates as one operating segment for financial reporting purposes. The Company's principal products are IOLs used in cataract surgery and ICLs used in refractive surgery. 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 seek to delight patients and surgeons by:

·Improving patient outcomes;

·Minimizing patient risk; and

·Simplifying 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 and marketed 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 our intellectual property surrounding the design and production of our biocompatible Collamer material and the production of ICLs. 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. 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, superior cosmetic appearance, and poses less risk of damage to the cornea.

The ICL has been implanted into more than 550,000 eyes worldwide. STAAR began selling the ICL for myopia for use outside the U.S. in 1996. U.S. sales commenced in 2006. STAAR is the only company with FDA approval to sell a posterior chamber phakic IOL (such as our ICL) in the U.S. In September 2011, STAAR launched the ICL with CentraFLOW technology, which uses a port in the center of the ICL optic in ex-U.S. markets. 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. The CentraFLOW technology makes the visual outcomes of the ICL available through a simpler and more comfortable surgical implantation experience. We are able to sell the TICL and the ICL with CentraFLOW technology in the following ex-U.S. regions: the 33 countries that require the European Union CE Mark, China, Canada (at present, TICL only), Korea, Japan, India, Brazil, Singapore, and several countries in the Middle East. STAAR submitted its application for U.S. approval of the TICL to the FDA in 2006, and our application remains under review (see "Regulatory Matters – Regulatory Requirements in the United States"). In December 2015, we received CE Mark for V5, an ICL with CentraFLOW technology and also an expanded optical zone up to 20%. We believe the expanded optical zone may further improve certain patients' visual experience, thus making the ICL increasingly desirable for both patients and surgeons.

The Hyperopic ICL, which treats far-sightedness, is sold primarily in countries that require the European Union CE Mark.

Globally, the ICL is available for myopia and hyperopia and is available in multiple models, powers 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 TICL 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 customarily make the TICL to order. In 2015, we shipped approximately 78% of TICL orders in less than one week from receipt.

Sales of ICLs (including TICLs) accounted for approximately 67% of our total sales in fiscal 2015, 59% of our total sales in fiscal 2014, and 61% of our total sales in fiscal 2013.

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 a micro- incision less than 3mm in length. 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 of the countries where STAAR does business, 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 for STAAR and our customers 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 a premium lens, such as STAAR's Toric IOL, and associated services.

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, give 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 that can be delivered through a micro-incision using STAAR's nanoPOINT Injection System.

We have developed and currently market 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 parts of 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. 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.

Sales of IOLs accounted for approximately 26% of our total sales in fiscal 2015, 33% of our total sales in fiscal 2014, and 33% of our total sales in fiscal 2013.

Other Surgical Products

We also sell other related instruments and devices that we manufacture or that are manufactured by others, but generally these products have lower overall gross profit margins relative to our ICLs and IOLs. 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 7% of our total sales in fiscal 2015, 9% of our total sales in fiscal 2014, and 5% of our total sales in fiscal 2013.

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. 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, know-how and other intellectual property directly related and important to our business. As of January 1, 2016, we owned 27 United States and foreign patents and had 26 patent applications pending. In addition, as of January 1, 2016, our Japanese subsidiary owned 48 Japanese and foreign patents and had 2 patent applications pending. We believe that no particular patent is so important that its loss or expiration would materially adversely affect our operations as a whole. Our patents, including blocking patents, have expiration dates from 2016 through 2029.

Our intellectual property generally relates to the design, production and manufacture of the Collamer lens material, ICLs, IOLs, and lens delivery systems for folding intraocular lenses (injectors and cartridges, both stand-alone and preloaded) used with ICLs and IOLs. We believe it would require extensive time and effort for a competitor to duplicate our intellectual property and processes to develop a product with comparable capabilities to our ICL or IOL product lines.

Worldwide, we sell all of our major products under trademarks we consider to be important to our business. STAAR®, Visian®, Collamer®, CentraFLOW®, AquaPORT®, nanoFLEX® nanoPOINT™, Epiphany® and AquaFlow™ are trademarks or registered trademarks of STAAR in the U.S. and other countries. Collamer® is the brand name for STAAR’s proprietary collagen copolymer lens material. 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. We cannot provide any assurance that employees and consultants will abide by the confidentiality or other terms of their agreements. Despite measures taken to protect our intellectual property, unauthorized parties may copy aspects of our products or obtain and use information that we regard as proprietary.

Seasonality

Seasonality does not materially affect our sales in the first, second or fourth quarter. Sales in the third quarter may be lower due to the summer vacation effect in Europe.

Working Capital Requirements

There are no special inventory requirements or credit terms extended to customers that would have a material adverse effect on our working capital.

Distribution and Customers

We market our products to a variety of health care providers, including surgical centers, hospitals, managed care providers, health 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, Germany, the U.K. and Spain and, supplemented by independent distributors, in approximately 60 additional 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.

Two customers, Shanghai Langsheng, our China distributor, and WooJeon Medical Co., Ltd., our Korean distributor, each accounted for more than 10% of our consolidated net sales during fiscal 2015.

Net sales to Shanghai Langsheng during each of the last three fiscal years were as follows:

Net Sales to Shanghai Langsheng

Fiscal Year	Net Sales ($, in thousands)	Net Sales as Percentage of Consolidated Net Sales	
2015	$ 11,851	15.4	%
2014	$ 7,990	10.7	%
2013	$ 7,191	10.0	%

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	
2015	$ 8,061	10.5	%
2014	$ 6,563	8.8	%
2013	$ 7,743	10.7	%

Backlog

The dollar amount of STAAR’s backlogged orders is not material in relation to total annual sales. We generally keep sufficient inventory on hand to ship product immediately or shortly after receipt of an order.

Government Contracts

No material portion of our business is subject to renegotiation of profits or termination of any particular contract or subcontract 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 products 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. In the cataract surgery market, our IOLs primarily compete based on our technology's quality and value.

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 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 by AMO under the Verisyse® brand), and (3) angle-supported anterior chamber PIOLs like the Cachet® made by Novartis (formerly Alcon) which has been sold outside the U.S. We believe the ICL has compelling clinical advantages over the other lenses, which are reflected in our strong market share of the global phakic IOL market. The ICL is the only foldable, minimally invasive PIOL approved for sale in the U.S. Competitors from a low cost manufacturing geography are beginning to appear in the market with their version of an implantable contact lens, which we believe so far have not materially impacted our global sales.

The global cataract market is highly concentrated, with the top three competitors (Alcon, Abbott Medical Optics, and Bausch & Lomb) combined accounting for approximately 68% of total market revenue, according to a 2015 report by Market Scope, LLC, a publisher of ophthalmic industry analysis.

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.

Regulatory Matters

Nearly all countries where we sell our products have regulations requiring premarket clearance or approval of medical devices by governmental or regulatory authorities. Various federal, state, local and foreign laws also apply to our operations, including, among other things, working conditions, laboratory, clinical, advertising and promotions, and design 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 rigorous requirements comparable to those established by the U.S. Food and Drug Administration (FDA). Obtaining clearance or approval to distribute medical products is complex, 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 any 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, be as broad in scope as we seek, or be conditioned on postmarket study requirements or restrictive labeling. We also cannot give any assurance that if our medical devices are approved for sale in a country, subsequent 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 Japan, 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, premarket clearance and approval, recordkeeping, reporting, advertising, promotion, post-market surveillance, and import and export of medical devices.

Most of our products are classified as 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 premarket approval (PMA) from the FDA, unless specifically exempted by the agency or subject to another form of FDA premarket review. 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 (premarket approval (PMA) required before commercial marketing). Devices deemed to pose lower risk are categorized as either Class I (low risk) or II (moderate risk). Manufacturers of Class II devices are generally required to submit to the FDA a 510(k) premarket notification requesting clearance of the device for commercial distribution in the United States. Most low risk (Class I) devices and some Class II 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 (ODE).

510(k) Clearance. Our lens injector systems are Class I devices subject to the 510(k) premarket 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) premarket 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) premarket notifications are cleared without clinical data, in some cases, the FDA requires significant clinical data to support substantial equivalence. In reviewing a premarket 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 premarket 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 premarket approval for any modifications to a previously cleared product, we may be required to cease marketing or recall the modified device until we obtain this clearance or approval. Also, in these circumstances, we may be subject to significant regulatory fines or penalties.

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, validation, documentation, complaint handling, supplier control, 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 conduct of additional post-approval clinical studies or 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 limited changes prior to the FDA's review of a 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) premarket notification. Clinical trials conducted to support premarket clearance or approval 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. All FDA-regulated clinical studies, whether significant or non-significant risk, must be approved and overseen by the appropriate institutional review boards (IRBs) at the clinical trial sites, and informed consent of the patients participating in the clinical trial must be 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 United States 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, clinical study and other regulations. Both before and after we receive premarket 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, product complaints and manufacturers' required reports of adverse experiences, product corrections and removals, 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 Regulation (QSR) and other requirements, such as requirements for advertising and promotion. The Good Manufacturing Practice (GMP) regulations for medical devices embodied in the QSR govern the methods used in, and the facilities and controls used for, the design, manufacture, packaging, labeling, 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, reliable, 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. In the case of devices subject to pending premarket clearance or approval applications, FDA has broad authority to halt the review of applications and require significant additional data analyses, audits, and other corrective actions where clinical data contained in an application are deemed to be actually or potentially unreliable, inaccurate, or not in compliance with clinical study or good clinical practice requirements.

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. In February 2010 and November 2011, we received letters of deficiency from the FDA outlining additional questions. After several communications with and additional data submissions to the FDA, on March 14, 2014 an FDA Ophthalmic Devices Panel of the Medical Devices Advisory Committee, which 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 (2014 Warning Letter) citing alleged violations of current good manufacturing practice (cGMP) regulations that were identified by the FDA during an inspection of our 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 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 2014 Warning Letter and the 2015 FDA-483 and is concurrently continuing to implement its corrective action plans relating to the 2014 Warning Letter and the 2015 FDA-483. STAAR has continued to submit monthly updates to FDA regarding its progress on corrective actions. 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 Patient Protection and Affordable Care Act of 2010, 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 of 2009, 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 Patient Protection 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 Pharmaceuticals and Medical Devices Agency (PMDA) in Japan. Our facilities in the United States, 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 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* (premarket 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 United States, 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 TICL, 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 with 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 MFDS 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. 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 prices we consider adequate.

Research and Development

We focus on furthering technological advancements in the ophthalmic products industry through the development of innovative premium ophthalmic products (lenses and companion delivery systems), materials and designs. We maintain active internal research and development programs. In order to achieve our business objectives, we will continue our investment in research and development.

During 2016, we intend to continue our focus on research and development in the following areas:

· Development of presbyopia-correcting ICLs;

· Development of preloaded injector systems for ICLs; and

· Beginning work on a new generation of ICLs and materials.

Our research and development expenses were approximately $14.8 million, $12.4 million, and $6.7 million for our 2015, 2014, and 2013 fiscal years, respectively. We expect to invest slightly in excess of 20% of sales in research and development in 2016. During 2015, our research and development expenses increased $2.4 million as compared to 2014, including increases of $1.4 million in validation related expenses, $600,000 in FDA remediation activities and $700,000 in clinical activities, partially offset by a decrease in project spending. The Company expects to continue its FDA remediation activities through 2016 and expects to spend approximately $2.1 million for these activities in 2016 as compared to approximately $4.0 million 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 February 15, 2016, we had approximately 360 employees.

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 - 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 rather than on the retinal surface. 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 unobtrusive area at the periphery of the iris to ensure continued fluid flow in the eye after implantation. The ICL with CentraFLOW technology 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 related visual pathway.

ophthalmic – of or related to the eye.

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

PRK – an acronym for photorefractive keratectomy, the first type of laser surgical operation to correct nearsightedness, farsightedness, or astigmatism.

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) regulation, 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, including requirements related to complaint handling and control of purchased or supplied services, components, and materials bearing on the quality of medical devices.

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 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 unpredictable and 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 may continue in the future.

We have reported losses in three of the past five years. Our near-term profitability is challenged by the competitive nature of our industry, continued investment in our operations, and the other risks to our business detailed herein. 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. 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, or could adversely affect our operations. Also, if we cannot continue to generate positive cash flow from operations, we may have to reduce our costs which could materially and adversely affect our ability to execute our operations and expand our business.

FDA compliance issues, including the 2014 Warning Letter and the 2015 FDA-483, may adversely impact our operations.

Quality system deficiencies observed at certain of our facilities during inspections have led to FDA Warning Letters and delays in product approvals until we resolve FDA concerns. On May 21, 2014, we received the 2014 Warning Letter from the FDA citing alleged violations of cGMP requirements of the Quality System Regulation (QSR) 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. The 2014 Warning Letter provides that, until we address 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 implement our corrective action plans related to both of these issuances and to update FDA monthly on our corrective actions. There can be no assurance when or if the FDA will be satisfied with our response to the 2014 Warning Letter or the 2015 FDA-483 or that FDA will lift the Warning Letter in any specific time frame, if at all. 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 TICL. While the TICL PMA supplement remains pending, we cannot predict when, or if, the FDA will grant approval of the TICL for use in the United States. In addition, we may be subject to additional regulatory action by the FDA, including fines, injunctions, warning letters, consent decrees, prosecution, civil money penalties, criminal penalties, repairs, replacements, refunds, recalls or seizures of products, total or partial suspension of production and marketing, the FDA's refusal to grant future premarket approvals, and/or withdrawals or suspensions of approvals or clearance for current products. Any such further action could, ultimately, be significant to our ongoing business and operations.

Our management expects to continue to devote significant resources and attention to our quality systems and compliance with QSR and other regulatory requirements for the foreseeable future. We cannot ensure that our efforts will be successful and failure to achieve or maintain compliance may adversely impact our business and operations, as noted above.

We rely and depend on independent distributors in international markets.

Except for the U.S., Japan, Spain, Germany, Canada, and the U.K. 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, and may be required to compensate the distributor for termination. Because these distributors are independent, 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 declining sales in that territory, harm to the reputation of our company or our products, or legal liability. For example, if either Shanghai Langsheng or WooJeon Medical Co., Ltd., each of whom accounted for more than 10% of our fiscal 2015 consolidated net sales, ceased to serve as our distributor, we may experience near term disruption in sales.

Unfavorable economic conditions or negative publicity concerning complications of laser eye surgery 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 with third parties. 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. Economic stagnation, lack of consumer confidence or new recessions in any of our larger markets could further slow ICL sales growth or, if severe, cause declines in sales. Because the ICL is our best selling and highest gross margin product, restricted growth or a decline in its sales could materially harm our business.

We believe that negative publicity in the past regarding the potential complications of refractive surgery and potential patient dissatisfaction, in particular as a result of LASIK and other corneal laser-based procedures, decreased patient interest 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 due to decreased patient interest in all refractive surgery.

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

The loss of a material supplier could significantly disrupt our business. In some cases, we obtain components used in certain of our products from single sources. If we experience difficulties acquiring sufficient quantities of required materials or products from our existing suppliers, or if our suppliers are found to be non-compliant with the FDA's QSR, other applicable laws, or STAAR’s requirements, qualifying and 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 verify the substitute supplier’s regulatory compliance and the quality standards of the replacement material could significantly delay production and materially reduce our sales.

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 it 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 material, polymer for injectors or acrylic lenses could also, for example, cause us material harm.

Further, any failure by us to forecast demand for or to maintain an adequate supply of, raw material and finished product could result in an interruption in the supply of certain products and a decline in the sales of that product. The manufacturing process to create the raw material necessary to produce some of our products is technically complex and requires significant lead-time. If our suppliers or we are unable or unwilling 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.

The global nature of our business may result in fluctuations and declines in our sales and profits due to fluctuations in foreign currency exchange rates and other international risks.

Activities outside the U.S. accounted for approximately 86% of our total sales during 2015. Foreign currency fluctuations could result in volatility of our revenue. 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. 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. We do not actively hedge our exposure to currency rate fluctuations. Also, 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 Future foreign currency fluctuations could favorably or unfavorably impact and increase the volatility of our revenue, profitability and stock price.

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. Further, fear of a pandemic disease may adversely affect sales, such as occurred in 2014 in Korea with the MERS disease.

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

We have accumulated approximately $131.1 million of U.S. federal tax net operating loss carryforwards as of January 1, 2016, which can be used to offset taxable income in future quarters if our U.S. operations become profitable. If unused, these tax loss carryforwards will begin to expire between 2020 and 2035. At this time, we do not believe our U.S. operations will generate sufficient profitability during the near term to enable us to use the totality of our net operating loss carryforwards before they expire. Also, currently if 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. If profits occur in the U.S. this will enable 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 or hinder us from realizing the benefits of the U.S. loss carryforwards. 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.

Because we manufacture most of our products from a single manufacturing site, if we suffer the partial or total loss of our Monrovia facility due to catastrophe, or if one of 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 such as equipment failure) 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.

Also, in our major markets, regulatory approval to manufacture materials and sell our products is generally limited to the current manufacturing site, and changing the site requires 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 and materials 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. Unanticipated delays or difficulties in manufacturing a transferred process or materials could interrupt our supply of products. Any sustained interruption in supply could cause us to lose market share and harm our business.

If any of our facilities were to experience a catastrophic loss, or if one of our 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.

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. It could be particularly detrimental if any key employee or employees went to work for a competitor. On February 11, 2016, one of our shareholders increased its beneficial ownership of the Company's common stock to approximately 26% of all shares outstanding. This event triggered the "Change in Control" provision in the Company's Amended and Restated 2003 Omnibus Equity Incentive Plan ("Plan"), which resulted in the immediate vesting of all unvested equity awards outstanding under the Plan. We cannot predict how this equity acceleration will impact key employees. Also, 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 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, makes for intense competition. Over the past several years, we have lost market share in IOL sales to some of our competitors. In addition, start-up competitors from a low cost manufacturing geography are beginning to appear in some markets with their version of an implantable contact lens.

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 Foreign Corrupt Practices Act (FCPA). Any failure to comply with these laws, even if inadvertent, could result in significant penalties or otherwise harm our reputation and business. Our reliance on foreign subsidiaries and independent distributors demands a high degree of vigilance in maintaining our policy against participation in corrupt activity. In many of our markets outside the U.S., doctors and hospital administrators may be deemed government officials. Other U.S. companies in the medical device and pharmaceutical field have faced criminal penalties under the FCPA for allowing their agents to deviate from appropriate practices in doing business with such individuals.

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.

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.

We determine our pension benefit obligations and funding status using many assumptions. 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 $3.9 million ($1.0 million for the Japan Plan and $2.9 million for the Swiss Plan) as of January 1, 2016.

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, emissions, and use of an irradiator and may subject us to environmental liability.

Our manufacturing, research and development activities involve the use of hazardous materials and equipment. 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 and equipment. 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 our information technology infrastructure for electronic communications among our locations around the world and between our personnel and our subsidiaries, customers, and suppliers. The integrity and protection of our customer, vendor, supplier, employee and other Company data, including data from the European Union, is an important part of our business. 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 employees, representatives 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.

Acquisitions of technologies, products, and businesses could disrupt our operations, 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, and mitigating the risk of unknown liabilities some of which may result in significant charges to earnings.

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, competitors, or others may use these channels to comment on the safety or 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 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 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.

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, and accepted by physicians and patients. 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 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 regulatory approval or commercial success.

Development of new implantable technology, from discovery through testing and registration to initial product launch, is expensive and time-consuming. 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.

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. as well as governmental authorities in those foreign countries in which we manufacture or distribute products, such as in Europe and Asia. The countries' 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.

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.

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 patient populations or uses of the product, or may otherwise limit our ability to promote, sell and distribute the product, or may require post-marketing studies or surveillance. 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 successfully 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.

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 have expired or are expiring 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.

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

As our patents expire, some of which expired over the past several years, our competitors may introduce products using the same technology. As a result of this possible increase in competition, we may lose sales and/or 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 and/or obtain new patents, our sales and profits with respect to our products could decline significantly. We may not be able to develop and successfully launch more advanced replacement products.

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 local laws targeting fraud and abuse in the healthcare industry, including anti-kickback and false claims laws. Violations of these laws are punishable by criminal or civil sanctions, including substantial fines, imprisonment and exclusion from participation in healthcare programs such as Medicare and Medicaid and health programs outside the United States. These laws and regulations are wide ranging and subject to changing interpretation and application, which could restrict our sales or marketing practices. Furthermore, since a number of our customers, particularly IOL customers, rely on reimbursement from Medicare, Medicaid and other governmental programs to cover a substantial portion of their expenditures, our exclusion from such programs as a result of a violation of these laws could have a material adverse effect on our business, results of operations, financial condition and cash flow.

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

We have voluntarily recalled our products in the past and similar recalls could take place again. We may also be subject to recalls initiated by manufacturers of products we distribute. We 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 and/or approved by regulatory authorities prior to distribution. 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.

Any changes in FDA or international regulations related to product approval, including those that apply retroactively, could adversely affect our competitive position and materially affect our business and financial results.

FDA and foreign regulations depend heavily on administrative interpretation, and we cannot assure you that future interpretations made by the FDA or other regulatory bodies, with possible retroactive effect, will not adversely affect us. Additionally, any changes, whether in interpretation or substance, in existing regulations or policies, or any future adoption of new regulations or policies by relevant regulatory bodies, could rescind, prevent or delay approval of our products, which could materially impact our competitive position, business, and financial results. Further, we or our distributors have obtained regulatory approvals outside the United States for many of our products, we or our distributors may be unable to maintain regulatory qualifications, clearances or approvals in these countries or obtain qualifications, clearances or approvals in other countries. If we are not successful in doing so, our business will be harmed.

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, agency enforcement actions and harm to our results.

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 international markets, such as European Union and Asian 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. In the future we may experience events that would require reporting to the FDA pursuant to the Medical Device Reporting (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.

Modifications to our products may require new marketing clearances or 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 premarket 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 and/or to recall the modified product until we obtain clearance or approval, and we may be subject to significant regulatory fines or penalties.

Regulatory agencies in other countries similarly require approval or clearance prior to our marketing or selling products in those countries. We rely on our distributors to obtain regulatory clearances or approvals of our products in certain countries outside of the United States. If we or our distributors are unable to obtain additional clearances or approvals needed to market existing or new products in the United States or elsewhere or obtain these clearances or approvals in a timely fashion or at all, or if our existing clearances or approvals are revoked or restricted, our revenues and profitability may decline.

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 manufacturing 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.

In addition, negative publicity about investigations or allegations of misconduct, even without a finding 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.

Risks Related to Ownership 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 $5.71 to $10.63 per share during the year ended January 1, 2016. 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 our 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.

Our charter documents, anti-takeover provisions of Delaware law, and contractual provisions 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 cannot act by written consent;
- certain 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.
- In addition, 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.

Ownership of our common stock is concentrated among a few investors, which may affect the ability of a third party to acquire control of us. Substantial sales by such investors could cause our stock price to decline.

Our largest three investors beneficially own more than 50% of our outstanding common stock. The sale of a substantial number of our shares by any such investor or our other stockholders within a short period of time could cause our stock price to decline, make it more difficult for us to raise funds through future offerings of our common stock or acquire other businesses using our common stock as consideration. Having such a concentration of ownership may have the effect of making it more difficult for a third party to acquire, or of discouraging a third party from seeking to acquire, a majority of our outstanding common stock or control of our Board of Directors through a proxy solicitation.

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 a 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

Certain of the legal proceedings in which we are involved are discussed under “Litigation and Claims” in Note 12, “Commitments and Contingencies,” to our Consolidated Financial Statements in this Annual Report on Form 10-K, and are hereby incorporated by reference.

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 1, 2016		
Fourth Quarter	$8.94	$7.14
Third Quarter	9.61	6.93
Second Quarter	10.63	7.29
First Quarter	9.09	5.71
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

Holders

As of February 17, 2016, there were approximately 381 record holders of our Common Stock.

Dividends

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

restricted by future agreements with lenders.

Stock Performance Graph

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

The following graph shows a comparison from December 31, 2010 through January 1, 2016 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); 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 December 31, 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.

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Total Returns Index for Fiscal Years:	2010	2011	2012	2013	2014	2015
STAAR Surgical Company	100.00	171.97	95.41	263.93	148.03	117.05
The Nasdaq Stock Market (US and Foreign Companies	100.00	99.15	114.22	161.42	186.32	199.69
Proxy Peer Group	100.00	88.22	92.96	111.84	112.97	132.94

Notes:

A. The lines represent monthly index levels derived from compounded daily returns that include all dividends.
B. These indexes are reweighted daily, using the market capitalization from 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 12/31/2010.

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 1, 2016, January 2, 2015, January 3, 2014, December 28, 2012 and December 30, 2011. The selected consolidated statement of operations data set forth below for each of the three most recent fiscal years, and the selected consolidated balance sheet data set forth below at January 1, 2016 and January 2, 2015 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 28, 2012 and December 30, 2011 and the consolidated balance sheet data set forth below at January 3, 2014, December 28, 2012, and December 30, 2011, 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.*"

	January 1, 2016	January 2, 2015	January 3, 2014	December 28, 2012	December 30, 2011
	(In thousands except per share data)				
Statement of Operations					
Net sales	$77,123	$74,987	$72,215	$63,783	$62,765
Cost of sales	24,400	26,164	21,906	19,492	20,396
Gross profit	52,723	48,823	50,309	44,291	42,369
General and administrative	19,604	18,287	16,771	15,150	14,932
Marketing and selling	23,695	25,879	23,888	21,281	17,726
Research and development	14,761	12,363	6,708	6,444	5,868
Other general and administrative expenses	—	321	2,242	2,636	1,060
Operating income (loss)	(5,337)	(8,027)	700	(1,220)	2,783
Total other income (expense), net	(268)	(618)	414	701	(79)
Income (loss) before income taxes	(5,605)	(8,645)	1,114	(519)	2,704
Income tax provision (benefit)	928	(253)	716	1,244	1,356
Net income (loss)	$(6,533)	$(8,392)	$398	$(1,763)	$1,348
Income (loss) per share from continuing operations – basic and diluted	$(0.17)	$(0.22)	$0.01	$(0.05)	$0.04
Net income (loss) per share – basic and diluted	$(0.17)	$(0.22)	$0.01	$(0.05)	$0.04
Weighted average shares outstanding-basic	39,260	38,091	36,706	36,253	35,434
Weighted average shares outstanding –diluted	39,260	38,091	38,607	36,253	36,878
Balance Sheet Data					
Working capital	$31,186	$28,526	$31,663	$26,125	$24,638
Total assets	62,954	58,911	61,931	54,759	49,006
Long-term obligations	6,221	5,441	4,667	5,068	5,532
Stockholders' equity	38,846	37,099	38,852	31,742	29,458

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

The matters addressed in this Item 7 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," "intend," "plan," "believe," "will," "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; statements of belief, including as to achieving 2016 business plans; expected regulatory activities and approvals, product launches, and any statements of assumptions underlying any of the foregoing.

Although we believe that the expectations reflected in these forward-looking statements are reasonable, such statements are inherently subject to risks and we can give no assurance that our 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 our control. These factors include, without limitation, those described in this Annual Report in "Item 1A. Risk Factors." We undertake 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

STAAR designs, develops, manufactures and sells premium implantable lenses and companion delivery systems for the eye. We are the world's leading manufacturer of intraocular lenses for patients seeking refractive vision correction, and we also make lenses for use in surgery to treat cataracts. All of the lenses we make are foldable, which allows the surgeon to insert them into the eye through a small incision during minimally invasive surgery. Refractive surgery is performed to treat the type of visual disorders that have traditionally been corrected using eyeglasses or contact lenses. We refer to our lenses used in refractive surgery as "implantable Collamer® lenses" or "ICLs." The field of refractive surgery includes both lens-based procedures, using products like our Visian ICL®, and laser-based procedures like LASIK. Successful refractive surgery can correct common vision disorders such as myopia, hyperopia and astigmatism. Cataract surgery is a common outpatient procedure where the eye's natural lens that has become cloudy with age is removed and replaced with an artificial lens called an intraocular lens (IOL) to restore the patient's vision. STAAR employs a commercialization strategy that focuses on achieving sustainable profitable growth. Our goal is to position the Visian ICL and TICL product lines throughout the world as primary and premium solutions for patients seeking visual freedom from wearing glasses or contact lenses while achieving excellent visual acuity through refractive vision correction.

See Item 1. "Business," for a discussion of:

- Operations
- Principal Products
- Distribution and Sales
- Competition
- Regulatory Matters
- Research and Development

2015 Overview and Strategic Priorities for 2016

In 2015, we devoted significant efforts towards improving our quality system and our remediation efforts. We added several new key employees, particularly in the Quality and Regulatory Affairs, Clinical and Medical Affairs, and Research and Development departments. Also we transitioned to a direct sales model in Germany and increased prices for our products on average by 6%.

In 2015, total ICL sales increased 17% primarily driven by higher ICL sales in each region, particularly Asia Pacific (APAC) and Europe, Middle East and Africa (EMEA), including increased adoption of the CentraFlow® technology in China where it was introduced in December 2014. These favorable impacts were partially offset by foreign

currency changes due to the strengthening U.S. dollar against the yen and euro, and lower IOL unit sales.

For 2016, our four strategic priorities are as follows:

1. FDA Remediation and Continuation of Quality Systems Overhaul: We expect to achieve our internal remediation and quality system plan commitments while also maintaining our global quality certifications, continuing to hire employees in the Quality and Regulatory departments, and acquiring additional equipment such as a Master Control Quality Management System;

2. Create the Visual Freedom Market for Implantable Lenses: Position the ICL as a primary and premium refractive procedure with clinical validation, new corporate and product branding, new digital and social media marketing, and by entering into strategic partnerships with large refractive surgical providers operating multiple eye hospitals and clinics;

3. Begin our Clinical Validation and Regulatory Rebirth: The expanded Global Clinical and Medical Affairs teams will assist in supporting submissions to and responding to queries from regulatory agencies and will monitor clinical data, conduct clinical studies, begin building patient registries and enhance medical communications protocol;

4. Innovating and Developing New Products, Materials and Delivery Systems: Expanding our R&D team, upgrading our labs and testing apparatus, and focusing on the priorities described above in Item 1, “Business” under “Research and Development.”

We expect double-digit ICL unit growth over the next 12 months driven primarily by increasing market acceptance of the Visian ICL with CentraFLOW technology in China and Europe, and a related positive impact on gross margins. We anticipate gross margins for full year 2016 to be higher than the fourth quarter of 2015. In addition, we expect continued investment in our operations, including, clinical affairs, corporate infrastructure and systems, marketing and research and development. We expect IOL sales in 2016 to be similar to IOL sales in 2015. We anticipate the 2016 operating expense rate as a percentage of sales to be slightly above the 2015 operating expense rate. We expect these investments to outpace revenue and gross margin expansion in the near term. We are evaluating our overall approach to the Cataract Care market and will determine our strategy by year-end 2016. We expect our lower margin injector parts will continue to be sold 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. During 2015, we spent approximately $4 million on our remediation efforts and expect to spend approximately $2 million in 2016. We expect to spend $4 million on capital expenditures relating to infrastructure and systems and $2 million on new branding and marketing efforts in 2016. We pay tax only, on our ex-U.S. business. In 2016, we expect these profits to be in the mid-single-digit range as a percentage of ex-U.S. business sales.

Effective January 1, 2016, we entered into cooperation agreements with Aier Eye Hospital Group in China and Memira Eye Clinics in Sweden. Generally, under these agreements we will provide additional training, marketing and pricing support to these accounts in exchange for greater consideration of our products and participation in our patient registry, marketing, generating clinical data, and new product development efforts. We will seek to enter into similar arrangements with other customers in 2016. In December 2015 we entered into a license agreement with Santen Pharmaceuticals whereby we licensed out on a non-exclusive basis, certain rights to injector patents no longer material to us. In exchange, Santen paid a $300,000 licensing fee and agreed to a future milestone payment in the event of regulatory approval of any product that relies upon any of the licensed patent rights. We do not have any future commitments, deliverables or performance obligations to Santen in their efforts to pursue such regulatory approval in the future.

Finally, we will continue to evaluate opportunities to acquire new product lines, technologies and companies.

Immediate Vesting of All Unvested Equity Awards

On February 11, 2016, one of our shareholders increased its beneficial ownership of the Company's common stock to approximately 26% of all shares outstanding. This triggered the "Change in Control" provision in our Amended and Restated 2003 Omnibus Equity Incentive Plan ("Plan"), which resulted in the immediate vesting of all unvested equity awards outstanding under the Plan and us recording an aggregate $6.9 million non-cash charge to stock-based compensation in the consolidated statements of operations on that date. This charge will be recorded and included in the following categories of the consolidated statements of operations during the first quarter of fiscal year 2016: $3.3 million in general and administrative expenses, $1.2 million in marketing and selling expenses, $1.8 million in research and development expenses and $0.6 million in manufacturing costs.

As of the date of this report, there are approximately 3,654,000 exercisable stock options outstanding and no unvested awards outstanding under the Plan. See Note 18 to the consolidated financial statements.

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		
	January 1, 2016	January 2, 2015	January 3, 2014
Net sales	100.0%	100.0 %	100.0 %
Cost of sales	31.6 %	34.9 %	30.3 %
Gross profit	68.4 %	65.1 %	69.7 %
General and administrative	25.4 %	24.4 %	23.1 %
Marketing and selling	30.7 %	34.5 %	33.1 %
Research and development	19.1 %	16.5 %	9.3 %
Other general and administrative expenses	— %	0.4 %	3.1 %
Operating income (loss)	(6.9)%	(10.7)%	1.1 %
Total other income (expense), net	(0.3)%	(0.8)%	0.7 %
Income (loss) before income taxes	(7.3)%	(11.5)%	1.8 %
Provision (benefit) for income taxes	1.2 %	(0.3)%	1.0 %
Net income (loss)	(8.5)%	(11.2)%	0.8 %

* 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):

	2015	% of Total	2014	% of Total	2013
ICL	66.8 %	$51,543	58.7 %	$44,047	61.2 %	$44,128
IOL	25.8 %	19,857	32.5 %	24,336	33.4 %	24,153
Core Product Sales	92.6 %	71,400	91.2 %	68,383	94.6 %	68,281
Other	7.4 %	5,723	8.8 %	6,604	5.4 %	3,934
Total Sales	100.0%	$77,123	100.0%	$74,987	100.0%	$72,215

Net sales for 2015 were $77.1 million, a 2.8% increase over the $75.0 million reported in fiscal 2014. The increase in net sales was due to an increase in ICL sales of $7.5 million, partially offset by a $5.4 million decrease in IOLs and other product sales. Changes in foreign currency negatively impacted net sales by $2.4 million.

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.

Total ICL sales for 2015 were $51.5 million, a 17.0% increase from $44.0 million reported for fiscal 2014. The sales increase was driven by the APAC region, which grew 25% primarily due to a 48% increase in China sales and a 23% increase in Korea sales; followed by the EMEA region, which grew by 11% primarily due to a 73% increase in Germany sales, in part due to the transition to a direct sales model; and then by the NA region, which grew by 9%. Changes in foreign currency negatively impacted ICL sales by approximately $0.2 million. ICL sales represented 66.8% of our total sales for fiscal year 2015.

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 IOL sales were $19.9 million for fiscal 2015, a decrease of 18.4% over the $24.3 million reported in fiscal 2014. The decline was due to a planned hold on sales in Germany due to a distributer-to-direct conversion, a planned

phase-out of sales in China, continued softness in the U.S. and the impact of the weakening yen and euro against the U.S. dollar. Changes in foreign currency negatively impacted IOL sales by approximately $1.6 million. IOL sales represented 25.8% of our total sales for fiscal year 2015.

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 U.S., and China, and lower Collamer IOL sales in the U.S. 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.

Other product sales for the year ended January 1, 2016 were $5.7 million, a 13.4% decrease compared to the $6.6 million reported for the year ended January 2, 2015. The decrease in other product sales is due to a decrease 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 $0.6 million. Other product sales represented 7.4% of our total sales for fiscal year 2015.

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.

Gross Profit

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

	2015	2014	2013
Gross Profit	$52,723	$48,823	$50,309
Gross Profit Margin	68.4 %	65.1 %	69.7 %

Gross profit for the year ended January 1, 2016 was $52.7 million, an 8.0% increase compared to the $48.8 million reported for the year ended January 2, 2015. Gross profit margin increased to 68.4% for the year, compared to 65.1% last year. The increase in gross profit margin is due to an increase in ICL product mix which has higher gross margins than our IOL products, improved ICL unit costs, and manufacturing improvements, partially offset by the negative impact of a weakening euro.

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 fiscal year 2014, compared to 69.7% for fiscal year 2013. 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.

General and Administrative Expense

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

	2015	2014	2013
General and Administrative Expense	$19,604	$18,287	$16,771
Percentage of Sales	25.4 %	24.4 %	23.2 %

General and administrative expense for the year ended January 1, 2016 was $19.6 million, a 7.2% increase compared to the $18.3 million reported for the year ended January 2, 2015. The increase in expense was primarily due to performance based bonuses and stock-based compensation.

General and administrative expense for the year ended January 2, 2015 was $18.3 million, a 9% increase compared to the $16.8 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.

Marketing and Selling Expense

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

	2015	2014	2013
Marketing and Selling Expense	$23,695	$25,879	$23,888
Percentage of Sales	30.7 %	34.5 %	33.1 %

Marketing and selling expense for the year ended January 1, 2016 was $23.7 million, an 8.4% decrease compared to the $25.9 million reported for the year ended January 2, 2015. The decrease in marketing and selling expense is due to decreased headcount, travel, and promotional activities in the U.S. and Japan, partially offset by an increase in costs associated with transitioning to direct distribution in Germany.

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.

Research and Development Expense

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

	2015		2014		2013	
Research and Development Expense	$14,761		$12,363		$6,708	
Percentage of Sales	19.1	%	16.5	%	9.3	%

Research and development expense for the year ended January 1, 2016 was $14.8 million, a 19.4% increase compared to the $12.4 million reported for the year ended January 2, 2015. The increase is primarily due to remediation and validation expenses and increased headcount. The Company expects its remediation efforts to continue through 2016 and estimates it will incur costs of approximately $2.1 million in 2016 related to these activities.

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.

Research and development expense consists 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 our research and development expense for the fiscal years presented (dollars in thousands):

	2015		2014		2013	
Other General and Administrative Expenses	—		$321		$2,242	
Percentage of Sales	—		0.4	%	3.1	%

Other general and administrative expenses in fiscal 2014 of $0.3 million, compared with $2.2 million in fiscal 2013, represents 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 Income (Expense), Net

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

	2015	2014	2013
Other Income (Expense), net	$(268)	$(618)	$414
Percentage of Sales	(0.3)%	(0.8)%	0.6 %

Other expense for the year ended January 1, 2016 was $0.3 million, compared to the $0.6 million of other expense reported for the year ended January 2, 2015, and $0.4 million of other income for the year ended January 3, 2014.

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

	Favorable (Unfavorable)	
	2015 v. 2014	2014 v. 2013
Interest income	$ (1)	$ (8)
Interest expense	26	16
Exchange losses	(53)	(935)
Royalty income	385	(67)
Other	(7)	(38)
Net change in other income (expense), net	$ 350	$ (1,032)

The increase in royalty income was primarily due to the $300,000 Santen licensing fee received in December 2015.

Provision (Benefit) for Income Taxes

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

	2015	2014	2013
Provision (Benefit) for Income Taxes	$928	$(253)	$716

The provision for income taxes increased from fiscal 2014 to fiscal 2015, primarily due to income tax expense of $928,000 recorded during the fiscal year 2015 generated from profits in our Swiss and Japan operations.

The provision for income taxes decreased from fiscal 2013 to fiscal 2014, primarily due to tax benefits of $1.4 million recorded 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 reduced our Swiss effective income tax rate commencing in 2015.

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 2016, 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 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 $2.1 million approximate cost in 2016 associated with our 2014 FDA Warning Letter and 2015 FDA-483 remediation efforts. 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):

	2015	2014	2013	2015 v. 2014	2014 v. 2013
Cash and cash equivalents	$13.4	$13.0	$22.9	$ .04	$ (9.9)
Current assets	$49.1	$44.9	$50.1	$ 4.2	$ (5.2)
Current liabilities	17.9	16.4	18.4	1.5	(2.0)
Working capital	$31.2	$28.5	$31.7	$ 2.7	$ (3.2)

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

Net cash used by operating activities was $2.2 million for fiscal year 2015 compared to cash used by operating activities of $8.0 million for fiscal year 2014 and cash provided by operations of $3.4 for fiscal year 2013. For 2015, net cash used in operating activities consisted of $6.5 million net loss, $2.3 million used for working capital and offset by non-cash operating activities of $6.7 million. 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.

Net cash used in investing activities was $2.0 million, $4.1 million, and $3.4 million, for fiscal years 2015, 2014, and 2013, respectively, and relate primarily to the acquisition of property, plant and equipment. The decrease in investment in property, plant and equipment during 2015, relative to 2014, was primarily due to the investments made in connection with the relocation of all manufacturing to the Company's Monrovia, CA facility which was completed during 2014. 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.

Net cash provided by financing activities was $4.6 million, $2.5 million, and $2.4 million for fiscal years 2015, 2014, and 2013, respectively. For 2015, net cash provided by financial activities consisted of $2.2 million of proceeds from the exercise of stock options and $2.8 million in proceeds from the exercise of warrants, partially offset by $0.4 million in repayment of capital lease obligations. For 2014, net cash provided by financial activities consisted of $3.0 million of proceeds from the exercise of stock options, partially offset by $0.5 million in repayment of capital lease obligations.

Accounts receivable was $15.7 million as of January 1, 2016 and $11.1 million as of January 2, 2015. Days' Sales Outstanding (DSO) was 74 days in 2015 and 54 days in 2014.

Inventories at the end of fiscal 2015 and 2014 were $15.9 million and $15.7 million, respectively. Days' Inventory on Hand (DOH) was 178 days in 2015 and 155 days in 2014 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 1, 2016), at an interest rate equal to the Tokyo short-term prime interest rate (approximately 1.475% as of January 1, 2016) and may be renewed annually (the current line expires on September 30, 2016). 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 2016. The Company had 500,000,000 Yen outstanding on the line of credit as of January 1, 2016 and January 2, 2015, (approximately $4.2 million based on the foreign exchange rates on January 1, 2016 and January 2, 2015, respectively) which approximates fair value due to the short-term maturity and market interest rates of the line of credit. As of January 1, 2016, 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 1, 2016), 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 1, 2016 and January 2, 2015.

On May 1, 2015, STAAR Surgical AG entered into a guarantee agreement with Bankinter. The agreement, as amended, provides Bankinter with a guarantee of up to EUR 200,000 (approximately $217,000 at the rate of exchange on January 1, 2016) for trade receivables from the Company's Spanish customers. The total guarantee amount is offset against the credit agreement in place with Credit Suisse and therefore reduces the credit line available to STAAR Surgical AG for working capital requirements to up to 783,000 Swiss francs (approximately up to $783,000 at the rate of exchange on January 1, 2016). Unless terminated sooner by Bankinter, the guarantee agreement expires on May 1, 2017.

Covenant Compliance

The Company is in compliance with the covenants of its credit facilities and lines of credit as of January 1, 2016.

Contractual Obligations

The following table represents the Company's known contractual obligations as of January 1, 2016 (in thousands):

	Payments Due by Period				
Contractual Obligations	Total	1 Year	**2-3 Years**	**4-5 Years**	**More Than 5 Years**
Line of credit	$4,159	$4,159	$—	$—	$ —
Capital lease obligations	592	384	208	—	—
Operating lease obligations	5,526	1,657	2,089	1,346	434
Pension benefit payments	1,806	113	326	262	1,105
Severance	133	133	—	—	—
Open purchase orders	161	161	—	—	—
Total	$12,377	$6,607	$2,623	$1,608	$ 1,539

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 certain customers and for our STAAR Japan subsidiary, which is typically recognized when the product is received by the customer. We do 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 to ophthalmic surgeons, hospitals, ambulatory surgery centers, vision centers, and distributors for use by surgeons who have already been certified in their implantation, 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 earn 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 our 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 and 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, which contain a service condition such that they vest if the grantee is still employed with us on a range of measurement dates, which are typically three years after the grant date. On occasion, we also issue RSUs

- to certain employees which contain a performance condition such that they vest if the internally established 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. On February 11, 2016, a change in control occurred under the Amended and Restated 2003 Omnibus Equity Plan resulting in the immediate vesting of all unvested equity awards outstanding under the plan. (See Note 18 to the consolidated financial statements).

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. 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 3 to 20 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 our 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 or loss. 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 has adversely affected our ability to purchase or sell products at agreed upon prices. No assurance can be given, however, that adverse currency exchange rate fluctuations will not occur in the future, which could significantly affect our operating results. We do not currently hedge transactions to offset changes in foreign currency.

Inflation

Management believes inflation has not had a significant impact on our net sales and revenues and on income from continuing operations during the past three years.

Off Balance Sheet Arrangements

We did not have any off-balance sheet arrangements during the year ended January 1, 2016, except for the guarantee agreement we have with Bankinter, a Spanish bank, to guarantee up to EUR 200,000 in trade receivables from our Spanish customers. See Note 8 to our consolidated financial statements.

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 1, 2016, 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 1, 2016). 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, net 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 1, 2016, 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 1, 2016 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 1, 2016, 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 1, 2016.

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 1, 2016, 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 1, 2016, 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 1, 2016 and January 2, 2015, and the related consolidated statements of operations, comprehensive loss, stockholders' equity, and cash flows for each of the three years in the period ended January 1, 2016 and our report dated March 10, 2016 expressed an unqualified opinion thereon.

/s/ BDO USA, LLP

Costa Mesa, California

March 10, 2016

Item 9B. Other Information

None

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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 2016 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 1, 2016.

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	Restated Certificate of Incorporation.(1)
3.2	Amended and Restated Bylaws.(2)
4.1	Form of Certificate for Common Stock, par value $0.01 per share.(3)
†4.2	Amended and Restated 2003 Omnibus Equity Incentive Plan and form of Option Grant and Stock Option Agreement.(4)
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.(5)
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.(5)
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)
10.18	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	Amended Credit Agreement between STAAR Japan Inc. and Mizuho Bank Ltd., dated December 28, 2012. (21)
10.21	Basic Agreement on Unsterilized Intraocular Lens Sales Transactions between Canon Staar Co., Inc. and Nidek Co., Ltd., dated May 23, 2005.(16)
10.22	Basic Agreement on Injector Product Sales Transactions between Canon Staar Co., Inc. and Nidek Co., Ltd., dated May 23, 2005.(16)
10.23	Memorandum of Understanding Concerning Basic Agreements for Purchase and Sale between STAAR Japan Inc. and Nidek Co., Ltd., dated December 25, 2008.(16)

10.24	Acrylic Preset supply Warranty Agreement between STAAR Japan Inc. and Nidek Co., Ltd., dated December 25, 2008.(16)
10.25	Framework Agreement for Loans between Credit Suisse and STAAR Surgical AG, dated August 12, 2010. (17)
†10.26	Form of Executive Severance Agreement.(18)
†10.27	Form of Executive Change In Control Agreement.(18)
10.28	Standard Industrial/Commercial Single – Tenant Lease – Net dated August 17 , 2012, by and between the Company and Pacific Equity Partners, LLC.(19)
†10.29	Letter of the Company dated March 27, 2012 to Samuel Gesten, Vice President and General Counsel, regarding compensation.(21)
†10.30	Letter of the Company dated August 10, 2012 to James Francese, Vice President, Global Marketing, regarding compensation. (21)
†10.38	Letter of the Company dated July 27, 2015 to Keith Holliday, Vice President of Research and Development, regarding compensation. (21)
†10.32	Letter of the Company dated August 7, 2013 to Stephen Brown, Vice President of Finance, and Chief Financial Officer, regarding compensation.(20)
10.33	**Amendment Agreement between STAAR Surgical AG and Nidek Co., Ltd., dated April 11, 2014.(23)
†10.34	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	The following materials from the Company's Annual Report on Form 10-K for the year ended January 1, 2016 formatted in Extensible Business Reporting Language (XBRL): (i) the Consolidated Balance Sheets, (ii) the Consolidated Statements of Income, (iii) the Consolidated Statements of Comprehensive Loss, (iv) the Consolidated Statements of Stockholder Equity, (v) the Consolidated Statements of Cash Flows, and (vi) related notes.

* Filed herewith.

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

*** Furnished herewith.

† Management contract or compensatory plan or arrangement.

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

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

(2) Incorporated by reference from the Company's Current Report on Form 8-K as filed on December 17, 2015.

(3) 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.

(4) Incorporated by reference to the Company's Current Report on Form 8-K, as filed on March 1, 2016.

(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 10, 2001.

(7) Incorporated by reference to the Company's Annual Report on Form 10-K, for the year ended January 2, 2004, as filed on March 17, 2004.

(8) Incorporated by reference from the Company's Annual Report on Form 10-K, for the year ended January 2, 1998, as filed on April 1, 1998.

(9) Incorporated by reference from the Company's Quarterly Report on Form 10-Q, for the period ended June 29, 2012, as filed on August 8, 2012.

(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.

(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 with the Commission on September 9, 2013.

(21) Incorporated by reference to the Company's Quarterly Report on Form 10-Q for the period ended October 2, 2015, as filed on November 4, 2015.

(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 10, 2016 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 Caren Mason	President, Chief Executive Officer and Director (principal executive officer)	March 10, 2016
/s/ Stephen P. Brown Stephen P. Brown	Vice President, Chief Financial Officer (principal accounting and financial officer)	March 10, 2016
/s/ Mark B. Logan Mark B. Logan	Chairman of the Board, Director	March 10, 2016
/s/ Stephen C. Farrell Stephen C. Farrell	Director	March 10, 2016
/s/ Richard A. Meier Richard A. Meier	Director	March 10, 2016
/s/ John C. Moore John C. Moore	Director	March 10, 2016
/s/ J. Steven Roush J. Steven Roush	Director	March 10, 2016
/s/ Louis E. Silverman Louis E. Silverman	Director	March 10, 2016

/s/ William P. Wall William P. Wall	Director	March 10, 2016

STAAR SURGICAL COMPANY AND SUBSIDIARIES

CONSOLIDATED FINANCIAL STATEMENTS

Years Ended January 1, 2016, January 2, 2015, and January 3, 2014

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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 1, 2016 and January 2, 2015 and the related consolidated statements of operations, comprehensive loss, stockholders' equity, and cash flows for each of the three years in the period ended January 1, 2016. In connection with our audits of the consolidated financial statements, we have also audited the consolidated financial statement 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 1, 2016 and January 2, 2015, and the results of their operations and their cash flows for each of the three years in the period ended January 1, 2016, 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 1, 2016, 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 10, 2016 expressed an unqualified opinion thereon.

/s/ BDO USA, LLP

Costa Mesa, California

March 10, 2016

STAAR SURGICAL COMPANY AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

January 1, 2016 and January 2, 2015

	2015	2014
	(In thousands, except par value amounts)	
ASSETS		
Current assets:		
Cash and cash equivalents	$13,402	$13,013
Accounts receivable trade, net	15,675	11,054
Inventories, net	15,921	15,717
Prepayments, deposits and other current assets	3,636	4,517
Deferred income taxes	439	596
Total current assets	49,073	44,897
Property, plant and equipment, net	10,095	10,066
Intangible assets, net	666	870
Goodwill	1,786	1,786
Deferred income taxes	717	695
Other assets	617	597
Total assets	$62,954	$58,911
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Line of credit	$4,159	$4,150
Accounts payable	6,691	6,620
Deferred income taxes	370	301
Obligations under capital leases	362	399
Other current liabilities	6,305	4,901
Total current liabilities	17,887	16,371
Obligations under capital leases	204	468
Deferred income taxes	1,888	1,704
Asset retirement obligations	156	115
Deferred rent	87	75
Pension liability	3,886	3,079
Total liabilities	24,108	21,812
Commitments and contingencies (Note 12)		
Stockholders' equity:		
Common stock, $0.01 par value; 60,000 shares authorized: 39,887 and 38,429 shares issued and outstanding at January 1, 2016 and January 2, 2015, respectively	399	384
Additional paid-in capital	187,007	178,232

Accumulated other comprehensive loss	(1,580)	(1,070)
Accumulated deficit	(146,980)	(140,447)
Total stockholders' equity	38,846	37,099
Total liabilities and stockholders' equity	$62,954	$58,911

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

STAAR SURGICAL COMPANY AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF OPERATIONS

Years Ended January 1, 2016, January 2, 2015, and January 3, 2014

	2015	2014	2013
	(In thousands, except per share amounts)		
Net sales	$77,123	$74,987	$72,215
Cost of sales	24,400	26,164	21,906
Gross profit	52,723	48,823	50,309
Selling, general and administrative expenses:			
General and administrative	19,604	18,287	16,771
Marketing and selling	23,695	25,879	23,888
Research and development	14,761	12,363	6,708
Other general and administrative expenses	—	321	2,242
Operating income (loss)	(5,337)	(8,027)	700
Other income (expense), net:			
Interest income	50	51	59
Interest expense	(128)	(154)	(170)
Gain (loss) on foreign currency transactions	(949)	(896)	39
Royalty income	740	355	422
Other income, net	19	26	64
Other income (expense), net	(268)	(618)	414
Income (loss) before provision (benefit) for income taxes	(5,605)	(8,645)	1,114
Provision (benefit) for income taxes	928	(253)	716
Net income (loss)	$(6,533)	$(8,392)	$398
Net income (loss) per share – basic	$(0.17)	$(0.22)	$0.01
Net income (loss) per share – diluted	$(0.17)	$(0.22)	$0.01
Weighted average shares outstanding – basic	39,260	38,091	36,706
Weighted average shares outstanding – diluted	39,260	38,091	38,607

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

STAAR SURGICAL COMPANY AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

Years Ended January 1, 2016, January 2, 2015, and January 3, 2014

	2015	2014	2013
	(In thousands)		
Net income (loss)	$(6,533)	$(8,392)	$398
Other comprehensive income (loss), net of tax:			
Foreign currency translation adjustment, net of tax	31	(955)	(1,327)
Pension liability adjustment, net of tax	(541)	(397)	29
Other comprehensive loss	(510)	(1,352)	(1,298)
Comprehensive loss	$(7,043)	$(9,744)	$(900)

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 1, 2016, January 2, 2015, and January 3, 2014

(**In thousands**)

	Common Stock Shares	Common Stock Par Value	Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss) (AOCI)	Retained Earnings (Accumulated Deficit)	**Total**
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	584	5	3,017	—	—	3,022
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
Net loss	—	—	—	—	(6,533)	(6,533)
Other comprehensive loss	—	—	—	(510)	—	(510)
Common stock issued upon exercise of warrants	700	7	2,793	—	—	2,800
Common stock issued upon exercise of options	476	5	2,163	—	—	2,168
Stock-based compensation	—	—	3,820	—	—	3,820
Unvested restricted stock	124	1	(1)	—	—	—
Vested restricted stock	158	2	—	—	—	2
Balance, at January 1, 2016	39,887	$ 399	$ 187,007	$ (1,580)	$ (146,980)	$ 38,846

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

STAAR SURGICAL COMPANY AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS

Years Ended January 1, 2016, January 2, 2015, and January 3, 2014

	2015	2014	2013
	(In thousands)		
Cash flows from operating activities:			
Net income (loss)	$(6,533)	$(8,392)	$398
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:			
Depreciation of property and equipment	2,196	2,078	1,711
Amortization of intangibles	205	382	440
Deferred income taxes	473	(841)	104
Fair value adjustment of warrant	—	—	(27)
Change in net pension liability	190	194	162
Loss on disposal of property and equipment	—	—	200
Stock-based compensation expense	3,304	4,663	4,489
Accretion of asset retirement obligation	—	3	10
Provision for sales returns and bad debts	345	182	263
Changes in working capital:			
Accounts receivable trade, net	(4,952)	(934)	(2,938)
Inventories, net	327	(3,943)	(1,603)
Prepayments, deposits and other current assets	856	(1,062)	(1,063)
Accounts payable	14	972	367
Other current liabilities	1,413	(1,253)	842
Net cash provided by (used in) by operating activities	(2,162)	(7,951)	3,355
Cash flows from investing activities:			
Acquisition of property and equipment	(2,045)	(4,054)	(3,448)
Sale of property and equipment	2	—	—
Net cash used in investing activities	(2,043)	(4,054)	(3,448)
Cash flows from financing activities:			
Repayment of capital lease lines of credit	(391)	(490)	(841)
Proceeds from the exercise of stock options	2,168	3,022	3,286
Proceeds from vested restricted stock	2	—	—
Proceeds from the exercise of warrants	2,800	—	—
Net cash provided by financing activities	4,579	2,532	2,445
Effect of exchange rate changes on cash and cash equivalents	15	(468)	(1,073)
Increase (decrease) in cash and cash equivalents	389	(9,941)	1,279

Cash and cash equivalents, at beginning of year	13,013	22,954	21,675
Cash and cash equivalents, at end of year	$13,402	$13,013	$22,954

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 first 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 1, 2016, 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 2015 is based on a 52-week period, 2014 is based on a 52-week period and fiscal year 2013 is based on a 53-week period.

Foreign Currency

The functional currency of the Company's Japanese subsidiary, STAAR Japan, Inc., 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 Statements of Comprehensive Loss. During 2015, 2014, and 2013, the net foreign translation gain (losses) were $31,000, $(955,000) and $(1,327,000), respectively, and net foreign currency transaction gains (losses), included in the consolidated statements of operations under other expenses, net were, $(949,000), $(896,000), and $39,000, 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 certain customers and for the STAAR Japan subsidiary, which is typically recognized when the product is received by the customer. The Company does not have significant deferred revenues as of January 1, 2016 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).

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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 GAAP 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 1, 2016, there was one customer with a trade receivable balance that represented 10% or more of consolidated trade receivables. As of January 2, 2015, there were two customers with trade receivables balances that represented 10% or more of consolidated trade receivables. 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.

There were two customers who accounted for 15% and 10% of the Company's consolidated net sales in fiscal 2015, one customer that accounted for 11% in fiscal 2014 and two customers that accounted for 10% and 11% in fiscal 2013.

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 (ASC 820-10-50):

- 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, prepayments 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 is 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. The Company performed its annual impairment test and determined that its goodwill was not impaired. As of January 1, 2016 and January 2, 2015, the carrying value of goodwill was $1.8 million.

Long-Lived Assets

The Company reviews property, plant, 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 1, 2016 and January 2,

2015 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 Costs

Advertising costs, which are included in marketing and selling expenses, are expensed as incurred. Advertising costs were $2.5 million, $2.8 million, and $2.1 million for fiscal 2015, 2014, and 2013, 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 and unvested restricted stock units, 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. See Note 15.

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 for executives and employees, and one year for members of its Board of Directors (see Notes 11 and 18).

The Company also, at times, issues restricted stock to its executive officers, employees, and members of its 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, for executives and employees, it is typically a three-year service period, and are subject to forfeiture (or acceleration, depending upon the circumstances) until vested or the service period is completed. Restricted stock compensation expense is recognized on a straight-line basis over the requisite service period of one to three years, 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, 15, and 18).

STAAR SURGICAL COMPANY AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The Company issues restricted stock units ("RSUs") (see Note 11), which can have only a service condition or a performance contingent restricted stock award based upon the Company meeting certain internally established performance conditions that vest only if those conditions are met or exceeded and the grantee is still employed with the Company. Restricted stock unit compensation expense is recognized on a straight-line basis over the requisite service period. The Company recognizes compensation cost for the performance condition 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, 15 and 18).

The Company accounts for options granted to persons other than employees and directors under ASC 505-50, *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.

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 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 1, 2016, January 2, 2015, and January 3, 2014 (in thousands):

	Foreign Currency Translation	Defined Benefit Pension Plan-Japan	Defined Benefit Pension Plan-Switzerland	Accumulated Other Comprehensive Income (Loss)
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)
Other comprehensive income (loss)	52	(38)	(576)	(562)
Tax effect	(21)	12	61	52
Balance at January 1, 2016	$ (145)	$ 95	$ (1,530)	$ (1,580)

Recent Accounting Pronouncements

In February 2016, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) 2016-02, “Leases (Topic 842)”, which requires lessees recognize assets and liabilities for leases with lease terms greater than twelve months in the statement of financial position. Leases will be classified as either finance or operating, with classification affecting the pattern of expense recognition in the income statement. ASU 2016-02 also requires improved disclosures to help users of financial statements better understand the amount, timing and uncertainty of cash flows arising from leases. The update is effective for fiscal years beginning after December 15, 2018, including interim reporting periods within that reporting period. Early adoption is permitted. The Company is currently evaluating the impact the adoption of ASU 2016-02 will have on its consolidated financial statements.

STAAR SURGICAL COMPANY AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

In November 2015, the FASB issued ASU 2015-17, “Income Taxes (Topic 740)”: Balance Sheet Classification of Deferred Taxes”, which changes how deferred taxes are classified on company’s balance sheets. The ASU eliminates the current requirement to present deferred tax liabilities and assets as current and noncurrent on the balance sheet. Instead, companies will be required to classify all deferred tax assets and liabilities as noncurrent. The amendments are effective for annual financial statements beginning after December 15, 2016, and interim periods within those annual periods. The Company is currently evaluating the impact the adoption of ASU 2015-17 will have on its consolidated financial statements.

In May 2014, the FASB issued ASU 2014-09, “Revenue from Contracts with Customers (Topic 606)”, which supersedes nearly all existing revenue recognition guidance under GAAP. The core principle of ASU 2014-09 is to recognize revenues when promised goods or services are transferred to customers in an amount that reflects the consideration to which an entity expects to be entitled for those goods or services. ASU 2014-09 defines a five-step process to achieve this core principle and, in doing so, more judgment and estimates may be required within the revenue recognition process than are required under existing GAAP.

The revised revenue standard is effective for public entities for annual periods beginning after December 15, 2017, and interim periods therein, using either of the following transition methods: (i) a full retrospective approach reflecting the application of the standard in each prior reporting period with the option to elect certain practical expedients, or (ii) a retrospective approach with the cumulative effect of initially adopting ASU 2014-09 recognized at the date of adoption (which includes additional footnote disclosures). The Company is currently evaluating the impact of the Company’s pending adoption of ASU 2014-09 on the Company’s financial statements and has not yet determined the method by which it will adopt the standard in fiscal 2018.

In July 2015, the FASB issued ASU 2015-11, “Simplifying the Measurement of Inventory” that replaces the existing accounting standards for the measurement of inventory. ASU 2015-11 requires a company to measure inventory at the lower of cost and net realizable value. Net realizable value is defined as the “estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal and transportation”. The effective date of ASU 2015-11 is for annual reporting periods beginning after December 15, 2016, including interim periods within those annual reporting periods. The Company does not expect the adoption of ASU 2015-11 will have a material effect on its consolidated financial statements.

Prior Year Reclassifications

Certain reclassifications have been made in the fiscal 2014 and 2013 financial statements to conform to the fiscal 2015 presentation. During the fiscal year ended January 1, 2016, the Company reclassified $127,000 and $203,000 presented as medical device excise tax in the consolidated statements of operations for the years ended January 2, 2015 and January 3, 2014, respectively, and included those expenses in general and administrative expenses for the current year presentation and, $75,000 from other current liabilities to other long-term liabilities in the consolidated balance sheet as of January 2, 2015 and related note disclosures to conform to current period's presentation.

Note 2 — Accounts Receivable Trade, Net

Accounts receivable trade, net consisted of the following at January 1, 2016 and January 2, 2015 (in thousands):

	2015	2014
Domestic	$1,728	$1,818
Foreign	15,824	10,825
	17,552	12,643
Less allowance for doubtful accounts and sales returns	1,877	1,589
	$15,675	$11,054

STAAR SURGICAL COMPANY AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 3 — Inventories, Net

Inventories, net consisted of the following at January 1, 2016 and January 2, 2015 (in thousands):

	2015	2014
Raw materials and purchased parts	$2,317	$2,146
Work in process	1,995	1,781
Finished goods	15,058	14,504
	19,370	18,431
Less inventory reserves	3,449	2,714
	$15,921	$15,717

Note 4 — Prepayments, Deposits, and Other Current Assets

Prepayments, deposits, and other current assets consisted of the following at January 1, 2016 and January 2, 2015 (in thousands):

	2015	2014
Prepayments and deposits	$1,386	$1,991
Income tax receivable	597	1,084
Value added tax (VAT) receivable	724	721
Deferred charge for foreign profits	182	338
Other current assets	747	383
	$3,636	$4,517

Note 5 — Property, Plant and Equipment, Net

Property, plant and equipment, net consisted of the following at January 1, 2016 and January 2, 2015 (in thousands):

	2015	2014
Machinery and equipment	$17,094	$15,674
Furniture and fixtures	6,980	6,535
Leasehold improvements	8,611	8,400
	32,685	30,609
Less accumulated depreciation	22,590	20,543
	$10,095	$10,066

Depreciation expense for the years ended January 1, 2016, January 2, 2015 and January 3, 2014, was approximately $2.2 million, $2.1 million, and $1.7 million, respectively.

Note 6 — Intangible Assets, Net

Intangible assets, net, consisted of the following (in thousands):

	January 1, 2016			January 2, 2015		
	Gross Carrying Amount	Accumulated Amortization	Net	Gross Carrying Amount	Accumulated Amortization	Net
Amortized intangible assets:						
Patents and licenses	$9,207	$ (8,891)	$316	$9,205	$ (8,859)	$346
Customer relationships	1,305	(1,044)	261	1,302	(911)	391
Developed technology	829	(740)	89	827	(694)	133
Total	$11,341	$ (10,675)	$666	$11,334	$ (10,464)	$870

STAAR SURGICAL COMPANY AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Aggregate amortization expense for intangible assets was $205,000, $382,000, and $440,000, for the years ended January 1, 2016, January 2, 2015 and January 3, 2014, respectively.

The following table shows estimated amortization expense for intangible assets for each of the next five succeeding years and thereafter (in thousands):

Fiscal Year	Amount
2016	$ 205
2017	205
2018	205
2019	51
Total	$ 666

Note 7 — Other Current Liabilities

Other current liabilities consisted of the following at January 1, 2016 and January 2, 2015 (in thousands):

	2015	2014
Accrued salaries and wages	$1,909	$1,647
Accrued income taxes	217	867
Accrued insurance	540	550
Accrued commissions	84	309
Accrued audit expense	314	352
Customer credit balances	203	186
Accrued severance	133	180
Accrued bonuses	2,114	75
Other[(1)]	791	735
	$6,305	$4,901

(1)No item in “Other” above exceeds 5% of total other current liabilities.

Note 8 — Liabilities

Lines 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, at an interest rate equal to the Tokyo short-term prime interest rate (approximately 1.475% as of January 1, 2016) and may be renewed annually (the current line expires on September 30, 2016). The credit facility is not collateralized. The Company had 500,000,000 Yen outstanding on the line of credit as of January 1, 2016 and January 2, 2015 (approximately $4.2 million based on the foreign exchange rates on January 1, 2016 and January 2, 2015, respectively), which approximates fair value due to the short-term maturity and market interest rates of the line of credit. In case of default, the interest rate will be increased to 14% per annum. As of January 1, 2016, there were no available borrowings under the line.

STAAR SURGICAL COMPANY AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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 borrowing of up to 1,000,000 CHF (Swiss Francs) ($1.0 million at the rate of exchange on January 1, 2016), 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 as defined in the agreement. There were no borrowings outstanding as of January 1, 2016 and January 2, 2015.

On May 1, 2015, STAAR Surgical AG entered into a guarantee agreement with Bankinter. The agreement, as amended, provides Bankinter with a guarantee of up to EUR 200,000 (approximately $217,000 at the rate of exchange on January 1, 2016) for trade receivables from the Company's Spanish customers. The total guarantee amount is offset against the credit agreement in place with Credit Suisse and therefore reduces the credit line available to STAAR Surgical AG for working capital requirements to up to 783,000 Swiss francs (approximately up to $783,000 at the rate of exchange on January 1, 2016). Unless terminated sooner by Bankinter, the guarantee agreement expires on May 1, 2017.

Covenant Compliance

The Company is in compliance with covenants of its credit facilities and lines of credit as of January 1, 2016.

Asset Retirement Obligation

The Company recorded certain Asset Retirement Obligations ("ARO"), in accordance with ASC 410-20 in connection with the Company's obligation to return its Japan facility to its "original condition", as defined in the lease agreement.

The Company has recognized the fair value of the ARO liability obligation included in noncurrent liabilities. The obligation is currently expected to be settled upon expiration of the lease in 2018. As of January 1, 2016, the Company has recorded approximately $156,000 in connection with its asset retirement obligation.

Note 9 — Income Taxes

The provision (benefit) for income taxes consists of the following (in thousands):

	2015	2014	2013
Current tax provision:			
U.S. federal (benefit)	$—	$3	$(121)
State	12	15	12
Foreign	443	570	721
Total current provision	455	588	612
Deferred tax provision (benefit):			
U.S. federal and state	—	—	—
Foreign provision (benefit)	473	(841)	104
Total deferred provision (benefit)	473	(841)	104
Provision (benefit) for income taxes	$928	$(253)	$716

As of January 1, 2016, the Company had federal net operating loss carryforwards of $131.1 million available to reduce future income taxes of its U.S. operations. The federal net operating loss carryforwards expire in varying amounts between 2020 and 2035. In California, the main state from which the Company conducts its domestic operations, the Company has state net operating losses of $45.7 million available to reduce future California income taxes. The California net operating loss carryforwards expire in varying amounts between 2016 and 2035 and, approximately $19.9 million of those net operating loss carryforwards, will expire over the next two years.

STAAR SURGICAL COMPANY AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The Company had accrued net income taxes receivable of $380,000 and $217,000 at January 1, 2016 and January 2, 2015, respectively, primarily due to taxes from foreign jurisdictions.

The provision (benefit) for income before taxes differs from the amount computed by applying the statutory federal income tax rate to income before taxes as follows (in thousands):

	2015		2014		2013	
Computed provision (benefit) for taxes based on income at statutory rate	34.0 %	$(1,905)	34.0 %	$(2,939)	34.0 %	$379
Increase (decrease) in taxes resulting from:						
Permanent differences	(0.6)	33	(0.2)	20	3.2	35
Federal minimum taxes	—	—	(0.1)	3	—	—
State minimum taxes, net of federal income tax benefit	(0.1)	8	(0.1)	10	0.7	8
Stock options			—	—	—	—
State tax benefit	(6.6)	370	4.6	(394)	6.4	71
Tax rate difference due to foreign statutory rate	1.6	(90)	3.3	(288)	43.7	487
Expiration of state net operating tax carryforwards	(47.3)	2,650	—	—	—	—
Foreign earnings not permanently reinvested	(9.8)	547	0.1	(11)	(7.7)	(86)
Foreign dividend withholding	(3.8)	211	(1.5)	132	12.5	140
Expiration of charitable contribution carryover	(0.3)	15	(0.2)	18	0.2	2
Reserve	—	—	—	—	(10.9)	(121)
Other	2.5	(140)	1.0	(85)	6.4	71
Valuation allowance	13.8	(771)	(38.0)	3,281	(24.2)	(270)
Effective tax provision (benefit) rate	(16.6)%	$928	2.9 %	$(253)	64.3 %	$716

The Company recorded an income tax provision of $928,000 during the fiscal year 2015 due to profits generated in its foreign operations. The Company recorded income tax benefits of $0.3 million during fiscal year 2014 principally related to its Swiss operations. The tax 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. The 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. The 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. The Company was advised by the STA during 2014 that it had met the special ruling qualifications for 2014.

Included in the state tax provision for 2015 is a decrease to the state deferred tax asset and corresponding decrease to the valuation allowance of $3,020,000 primarily related to the expiration of state net operating loss carryforwards. For 2014 there was an increase to the state deferred tax asset and corresponding increase to the valuation allowance of $394,000. For 2013 there was a decrease to the state deferred tax asset and corresponding decrease to the valuation allowance of $71,000. This results in a total state tax provision of $12,000 for 2015, $15,000 for 2014, and $12,000 for 2013.

STAAR SURGICAL COMPANY AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Included in the deferred foreign tax benefit for 2015 is an increase in foreign deferred liabilities of $172,000. For 2014, there was a decrease in foreign deferred liabilities of $1,039,000. For 2013, there was a decrease to the foreign deferred tax assets of $630,000 and a corresponding decrease to the valuation allowance of $1,008,000.

All earnings from the Company’s subsidiaries are not considered to be permanently reinvested. Accordingly, the Company provides withholding and U.S. taxes on all unremitted foreign earnings. During 2015 and 2014 there were no withholding taxes paid to foreign jurisdictions and there were no earnings repatriated from foreign subsidiaries.

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of the Company's deferred tax assets (liabilities) as of January 1, 2016 and January 2, 2015 are as follows (in thousands):

	2015	2014
Current deferred tax assets (liabilities):		
Allowance for doubtful accounts and sales returns	$90	$127
Inventories	422	511
Accrued vacation	382	397
Accrued other expenses	176	119
Other	57	80
Valuation allowance	(1,058)	(939)
Total current deferred tax assets (liabilities)	$69	$295
Non-current deferred tax assets (liabilities):		
Net operating loss carryforwards	$51,005	$53,747
Stock-based compensation	1,763	1,684
Business, foreign and AMT credit carryforwards	1,730	1,223
Capitalized R&D	134	423
Contributions	17	37
Pensions	583	489
Depreciation and amortization	695	870
Foreign tax withholding	(1,627)	(1,326)
Foreign earnings not permanently reinvested	(3,209)	(5,022)
Other	13	31
Valuation allowance	(52,275)	(53,165)

Total non-current deferred tax liabilities	$(1,171)	$(1,009)

As of January 1, 2016, the Company had net deferred tax liabilities in Switzerland of $1,686,000 (which included $1,627,000 of withholding taxes on unremitted foreign earnings) and net deferred tax assets of $584,000 in Japan included in the Company's components of deferred income tax assets and liabilities table. As of January 2, 2015, the Company had net deferred tax liabilities in Switzerland of $1,371,000 (which included $1,326,000 of withholding taxes on unremitted foreign earnings) and net deferred tax assets of $658,000 in Japan included in the Company's components of deferred income tax assets and liabilities table.

Valuation allowance

ASC 740 requires that a valuation allowance be established when it is more likely than not that all or a portion of a deferred tax asset may not be realizable.

STAAR SURGICAL COMPANY AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The Company is subject to income taxes in the U.S. and numerous foreign jurisdictions. In evaluating the Company's ability to recover the deferred tax assets within a jurisdiction from which they arise, management considers all available positive and negative evidence, including scheduled reversals of deferred tax liabilities, projected future taxable income, tax-planning strategies and results of recent operations. In projecting future taxable income, the Company begins with historical results and incorporates assumptions including overall current and projected business and industry conditions, the amount of future federal, state, and foreign pretax operating income, the reversal of temporary differences and the successful implementation of feasible and prudent tax-planning strategies. These assumptions require significant judgment about the forecasts of future taxable income and are consistent with the plans and estimates the Company uses to manage the underlying businesses. In evaluating the objective evidence that historical results provide, the Company considers three years of cumulative operating results. Valuation allowances, or reductions to deferred tax assets, are recognized if, based on the weight of all the available evidence, it is more likely than not that some portion or all of the deferred tax asset may not be realized.

U.S. Jurisdiction

Due to the Company's history of losses in the U.S., the valuation allowance fully offsets the value of U.S. deferred tax assets on the Company's balance sheet as of January 1, 2016. Further, pursuant to the provisions of Internal Revenue Code Section 382, significant changes in ownership may restrict the future utilization of these tax loss carry forwards.

Foreign Jurisdictions

STAAR Surgical AG

Due to STAAR Surgical AG's history of profits, the deferred tax assets are considered fully realizable. Included in deferred tax assets and liabilities of STAAR AG is noncurrent deferred tax assets of $312,000 and $256,000 as of January 1, 2016 and January 2, 2015, respectively.

STAAR Japan, Inc.

Since 2012, STAAR Japan functions as a limited-risk distributor with a guaranteed return from STAAR AG and accordingly, STAAR Japan's deferred tax assets are considered fully realizable. Included in deferred tax assets and liabilities of STAAR Japan is net deferred tax assets of $584,000 (as translated using the Japanese Yen exchange rate on January 1, 2016) and $658,000 as of January 1, 2016 and January 2, 2015, respectively.

Other Income Tax Disclosures

The following tax years remain subject to examination:

Significant Jurisdictions	Open Years
U.S. Federal	2012 – 2014
California	2011 – 2014
Switzerland	2014
Japan	2012 – 2014

Income (loss) from continuing operations before provision (benefit) for income taxes is as follows (in thousands):

	2015	2014	2013
Domestic	$(7,678)	$(8,113)	$(2,131)
Foreign	2,073	(532)	3,245
	$(5,605)	$(8,645)	$1,114

Note 10 — Employee Benefit Plans

The Company maintains a passive pension plan (the "Swiss Plan") covering employees of its Swiss subsidiary, which is accounted for as a defined benefit plan.

STAAR SURGICAL COMPANY AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Defined Benefit Plan-Switzerland

In Switzerland employers are required to provide a minimum pension plan for their staff. The Swiss Plan is financed by contributions of both the employees and employer. The amount of the contributions is defined by the plan regulations and cannot be decreased without amending the plan regulations. It is required that the employer contribute an amount equal to or greater than the employee contribution.

For the year ended, January 2, 2015, pursuant to the Manufacturing Consolidation Project, the Company terminated certain employees in its Swiss subsidiary resulting in Swiss pension plan curtailments as defined by ASC 715-30-35, *Defined Benefit Plans – Pensions, Settlements, Curtailments, and Certain Termination Benefits*. The curtailments resulted in a decrease of $1.6 million in the Swiss pension plan's projected benefit obligation, of which $0.9 million was used to distribute cash payments to employees resulting in a decrease in plan assets. The remaining $0.8 million was recorded as a curtailment gain measured in accordance with ASC 715-30-35-93.

However, since the Swiss pension plan's accumulated other comprehensive loss, immediately preceding the curtailments exceeded the curtailment gains, the curtailment gains were fully offset against the loss and no gain was recognized in earnings.

At January 2, 2015, the discount rate, one of the key assumptions used to calculate the Swiss pension plan's projected benefit obligation, was reduced from 2.5% to 1.4%, resulting in an increase to the projected benefit obligation of $0.7 million recorded through an increase in the accumulated other comprehensive loss account of the Swiss pension plan.

The following table shows the changes in the benefit obligation and plan assets and the Swiss Plan's funded status as of January 1, 2016 and January 2, 2015 (in thousands):

	2015	2014
Change in Projected Benefit Obligation:		

Projected benefit obligation, beginning of period	$4,827	$5,183
Service cost	316	297
Interest cost	74	114
Participant contributions	209	241
Benefits deposited (paid)	340	(116)
Actuarial loss on obligation	656	737
Prior service cost	(73)	—
Curtailments	—	(1,629)
Projected benefit obligation, end of period	$6,349	$4,827
Change in Plan Assets:		
Plan assets at fair value, beginning of period	$2,705	$3,517
Actual return on plan assets (including foreign currency impact)	35	(230)
Employer contributions	209	241
Participant contributions	209	241
Benefits deposited (paid)	340	(116)
Curtailment distributions	—	(948)
Plan assets at fair value, end of period	$3,498	$2,705
Funded status (pension liability), end of year	$(2,851)	$(2,122)
Amount Recognized in Accumulated Other Comprehensive Loss, net of tax:		
Actuarial loss on plan assets	$(822)	$(773)
Actuarial loss on benefit obligation	(1,668)	(902)
Actuarial gain recognized in current year	362	266
Effect of curtailments	606	528
Accumulated other comprehensive loss	$(1,522)	$(881)
Accumulated benefit obligation at end of year	$(5,932)	$(4,488)

STAAR SURGICAL COMPANY AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The underfunded balance of $2.9 million and $2.1 million was included in other long-term liabilities (pension liability) on the consolidated balance sheets as of January 1, 2016 and January 2, 2015, respectively.

Net periodic pension cost associated with the Swiss Plan during the years ended January 1, 2016, January 2, 2015 and January 3, 2014 include the following components (in thousands):

	2015	2014	2013
Service cost	$316	$297	$320
Interest cost	74	114	101
Expected return on plan assets	(93)	(97)	(96)
Actuarial loss recognized in current year	64	24	55
Net periodic pension cost	$361	$338	$380

Changes in other comprehensive income (loss), net of tax, associated with the Swiss Plan in the year ended January 1, 2016, January 2, 2015 and January 3, 2014 include the following components (in thousands):

	2015	2014	2013
Current year actuarial gain (loss) on plan assets, net of tax	$(61)	$(375)	$37
Current year actuarial gain (loss) on benefit obligation, net of tax	(635)	(846)	135
Actuarial gain recorded in current year, net of tax	57	28	46
Prior service cost	—	—	—
Effect of curtailments	—	782	—
Change in other comprehensive income (loss)	$(517)	$(411)	$218

The amount in accumulated other comprehensive income (loss) as of January 1, 2016 that is expected to be recognized as a component of the net periodic pension costs during fiscal year 2016 is $110,000.

Net periodic pension cost and projected and accumulated pension obligation for the Company’s Swiss Plan were calculated on January 1, 2016 and January 2, 2015 using the following assumptions:

	2015	2014
Discount rate	1.0 %	1.4 %
Salary increases	2.0 %	2.0 %
Expected return on plan assets	2.5 %	3.0 %
Expected average remaining working lives in years	10.4	10.1

The discount rates are based on an assumed pension benefit maturity of 10 to 15 years. The rate was estimated using the rate of return for high quality Swiss corporate bonds that mature in eight years. This maturity was used as there are significant numbers of high quality Swiss bonds, but very few bonds issued with maturities with longer lives. In order to determine an appropriate discount rate, the eight year rate of return was then extrapolated along the yield curve of Swiss government bonds.

STAAR SURGICAL COMPANY AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The salary increase rate was based on the Company's best estimate of future increases over time.

The expected long-term rate of return on plan assets is based on the expected asset allocation and assumptions concerning long-term interest rates, inflation rates, and risk premiums for equities above the risk-free rates of return. These assumptions take into consideration historical long-term rates of return for relevant asset categories

Under Swiss law, pension funds are legally independent from the employer and all the contributions are invested with regulated entities. The Company has a contract with Allianz Suisse Life Insurance Company's BVG Collective Foundation (the "Foundation") to manage its Swiss pension fund. Multiple employers contract with the Foundation to manage the employers' respective pension plans. The Foundation manages the pension plans of its contracted employers as a collective entity. The investment strategy is determined by the Foundation and applies to all members of the collective Foundation. There are no separate financial statements for each employer contract. The pension plan assets of all the employers that contract with the Foundation are comingled. They are considered multiple-employer plans under ASC 715-30-35-70 and therefore accounted for as single-employer plans.

As there are no separate financial statements for each employer contract, there are no individual investments that can be directly attributed to the Company's pension plan assets. However, the funds contributed by an employer are specifically earmarked for its employees and the total assets of the plan allocable to Company's employees are separately tracked by the Foundation. The lack of visibility into the specific investments of the plan assets and how they are valued is considered to be a significant unobservable input, therefore, the Company considers the plan assets collectively to be Level 3 assets under the fair value hierarchy (see Note 1).

Plan assets totaled $3.5 million and $2.7 million as of January 1, 2016 and January 2, 2015, respectively.

The table below sets forth the fair value of Plan assets at January 1, 2016 and January 2, 2015, and the related activity in fiscal years 2014 and 2015, in accordance with ASC 715-20-50-1(d) (in thousands):

	Insurance Contracts (Level 3)
Beginning balance at January 3, 2014	$3,517
Actual return on plan assets	(230)
Purchases, sales and settlement	(582)
Ending balance at January 2, 2015	2,705
Actual return on plan assets	35
Purchases, sales and settlement	758
Ending balance at January 1, 2016	$3,498

During fiscal 2016, the Company expects to make cash contributions totaling approximately $248,000 to the Swiss Plan.

The estimated future benefit payments for the Swiss Plan are as follows (in thousands):

Fiscal Year	Amount
2016	$ 58
2017	65
2018	72
2019	72
2020	78
Thereafter	498
Total	$ 843

STAAR SURGICAL COMPANY AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Defined Benefit Plan-Japan

STAAR Japan maintains a noncontributory defined benefit pension plan ("Japan Plan") substantially covering all of the employees of STAAR Japan. Benefits under the Japan Plan are earned, vested and accumulated based on a point-system, primarily based on the combination of years of service, actual and expected future grades (management or non-management) and actual and future zone (performance) levels of the employees. Each point earned is worth a fixed monetary value, 1,000 Yen per point, regardless of the level grade or zone of the employee. Gross benefits are calculated based on the cumulative number of points earned over the service period multiplied by 1,000 Yen. The mandatory retirement age limit is 60 years old.

STAAR Japan administers the pension plan and funds the obligations of the Japan Plan from STAAR Japan's operating cash flows. STAAR Japan is not required, and does not intend, to provide contributions to the Plan to meet benefit obligations and therefore does not have any plan assets. Benefit payments are made to beneficiaries as they become due.

The funded status of the benefit plan at January 1, 2016 and January 2, 2015 is as follows (in thousands):

	2015	2014
Change in Projected Benefit Obligation:		
Projected benefit obligation, beginning of period	$957	$1,049
Service cost	121	157
Interest cost	6	9
Actuarial (gain) loss	32	(55)
Benefits paid	(83)	(66)
Foreign exchange adjustment	2	(137)
Projected benefit obligation, end of period	$1,035	$957
Changes in Plan Assets:		
Plan assets at fair value, beginning of period	$—	$—
Actual return on plan assets	—	—
Employer contributions	—	—
Benefits paid	—	—

Distribution of plan assets	—	—
Foreign exchange adjustment	—	—
Plan assets at fair value, end of period	$—	$—
Funded status (pension liability), end of period	$(1,035)	$(957)
Amount Recognized in Accumulated Other Comprehensive Income, Net of Tax:		
Transition obligation	$(20)	$(26)
Actuarial gain	122	146
Prior service cost	9	9
Net loss	(10)	(8)
Accumulated other comprehensive income	$101	$121
Accumulated benefit obligation at end of year	$(893)	$(828)

The underfunded balance of $1,035,000 and $957,000, respectively, was included in other long-term liabilities (pension liability) on the consolidated balance sheets as of January 1, 2016 and January 2, 2015.

STAAR SURGICAL COMPANY AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Net periodic pension cost associated with the Japan Plan for the years ended January 1, 2016, January 2, 2015 and January 3, 2014 includes the following components (in thousands):

	2015	2014	2013
Service cost	$121	$157	$158
Interest cost	6	9	8
Net amortization of transition obligation	11	12	12
Actuarial gain	(15)	(10)	(31)
Prior service cost (credit)	(2)	(1)	(1)
Net periodic pension cost	$121	$167	$146

Changes in other comprehensive income (loss), net of tax, associated with the Japan Plan for the years ended January 1, 2016, January 2, 2015 and January 3, 2014 include the following components (in thousands):

	2015	2014	2013
Amortization of net transition obligation	7	12	12
Amortization of actuarial loss	(21)	(9)	(47)
Actuarial income (loss) recorded in current year	(10)	13	(153)
Amortization prior service cost	—	(2)	(1)
Change in other comprehensive income (loss)	$(24)	$ 14	(189)

The amount in accumulated other comprehensive income (loss) as of January 1, 2016 that is expected to be recognized as a component of the net periodic pension cost in fiscal 2016 is approximately $1,900.

Net periodic pension cost and projected and accumulated pension obligation for the Company’s Japan Plan were calculated on January 1, 2016 and January 2, 2015 using the following assumptions:

	2015	2014
Discount rate	0.5 %	0.6 %
Salary increases	6.1 %	4.5 %
Expected return on plan assets	N/A	N/A
Expected average remaining working lives in years	8.13	8.12

The discount rate of 0.50% as of January 1, 2016 and the discount rate of 0.60% as of January 2, 2015 are based on the approximate Japanese government bond rate with a term of 10 to 20 years.

The salary increase average rate was based on the Company’s best estimate of future increases over time.

The estimated future benefit payments for the Japan Plan are as follows (in thousands):

Fiscal Year	Amount
2016	$ 55
2017	135
2018	54
2019	55
2020	57
Thereafter	607
Total	$ 963

STAAR SURGICAL COMPANY AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Defined Contribution Plan

The Company maintains a 401(k) profit sharing plan ("401(k) Plan") for the benefit of qualified employees in U.S. During the fiscal year ended January 1, 2016, employees who participate may elect to make salary deferral contributions to the 401(k) Plan up to the $18,000 of the employees' eligible payroll subject to annual Internal Revenue Code maximum limitations (with a $6,000 annual catch-up contribution permitted for those over 50 years old). The Company contribution percentage is 80% of the employee's contribution up to the first 6% of the employee's compensation. In addition, STAAR may make a discretionary contribution to qualified employees, in accordance with the 401(k) Plan. During the years ended January 1, 2016, January 2, 2015, and January 3, 2014, the Company made contributions, net of forfeitures, of $625,000 $518,000, and $270,000, respectively, to the 401(k) Plan.

Note 11 — Stockholders' Equity

The cost that has been charged against income for stock-based compensation is set forth below (in thousands):

	Fiscal Year Ended		
	January 1, 2016	**January 2, 2015**	**January 3, 2014**
Employee stock options	$2,306	$ 2,842	$ 2,683
Restricted stock	485	935	999
Restricted stock units	452	795	589
Consultant compensation	61	91	218
Total	$3,304	$ 4,663	$ 4,489

The Company recorded stock-based compensation expense in the following categories on the accompanying consolidated statements of operations (in thousands):

	Fiscal Year Ended		
	January 1, 2016	January 2, 2015	January 3, 2014
Cost of Sales	$52	$ 108	$ 77
General and administrative	2,090	2,552	2,586
Marketing and selling	696	1,065	1,167
Research and development	466	938	659
Total stock-based compensation expense	3,304	4,663	4,489
Amounts capitalized as part of inventory	516	306	232
Total stock-based compensation	$3,820	$ 4,969	$ 4,721

There was no net income tax benefit recognized in the consolidated statements of operations for stock-based compensation expense for non-qualified stock options, as the Company fully offsets net deferred tax assets with a valuation allowance (see Note 9). The Company does not recognize deferred income taxes for incentive stock option compensation expense, and records a tax deduction only when a disqualified disposition has occurred (see Note 9).

As of January 1, 2016, there was $6.8 million of total unrecognized compensation cost related to non-vested share-based compensation arrangements granted under the Plan ($4.7 million for stock options and $2.1 million for restricted stock and restricted stock units). That cost was expected to be recognized over a weighted-average period of approximately two years. On February 11, 2016, under the Restated Omnibus Equity Incentive Plan, a change in control occurred resulting in the immediate vesting of all unvested equity awards outstanding under the Plan (see Note 18).

Stock Option Plan

The Amended and Restated 2003 Omnibus Equity Incentive Plan (“the Plan”) provides for various forms of stock-based incentives. To date, of the available forms of awards under the Plan, the Company has granted only stock options, restricted stock, unrestricted share grants, and restricted stock units (RSUs). Options under the plan are granted at fair market value on the date of grant, become exercisable generally over a three year period, or as determined by the Board of Directors, and expire over periods not exceeding 10 years from the date of grant. Certain option and share awards provide for accelerated vesting if there is a change in control and pre-established financial metrics are met (as defined in the Plan) (see Note 18). Grants of restricted stock outstanding under the Plan generally vest over periods of one to three years. Grants of RSUs outstanding under the Plan generally vest based on service, performance or a combination of both. As of January 1, 2016, there were 1,072,776 shares authorized and available for grants under the Plan.

STAAR SURGICAL COMPANY AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Assumptions

The fair value of each option award is estimated on the date of grant using a Black-Scholes option valuation model applying the weighted-average assumptions noted in the following table. Expected volatilities are based on historical volatility of the Company's stock. The expected term of options granted is derived from the historical exercises and post-vesting cancellations, and represents the period of time that options granted are expected to be outstanding. The Company has calculated a 7% estimated forfeiture rate based on historical forfeiture experience. The risk-free rate is based on the U.S. Treasury yield curve corresponding to the expected term at the time of the grant.

	Fiscal Year Ended		
	January 1, 2016	January 2, 2015	January 3, 2014
Expected dividend yield	0 %	0 %	0 %
Expected volatility	57 %	55 %	71 %
Risk-free interest rate	1.59%	1.29 %	0.73 %
Expected term (in years)	5.57	4.12	4.12

A summary of option activity under the Plan for the year ended January 1, 2016 is presented below:

Options	**Shares (000's)**	**Weighted-Average Exercise Price**	**Weighted-Average Remaining Contractual Term (years)**	**Aggregate Intrinsic Value (000's)**
Outstanding at January 2, 2015	3,175	$ 7.79		
Granted	1,155	7.81		
Exercised	(476)	4.56		

Forfeited or expired	(231)	10.57		
Outstanding at January 1, 2016	3,623	$ 8.02	6.59	$ 3,562
Exercisable at January 1, 2016	2,075	$ 7.15	4.85	$ 3,352

A summary of unvested options activity under the Plan for the year ended January 1, 2016 is presented below:

Options	**Shares**	Weighted-Average Grant-Date Fair Value
	(000's)	
Unvested at January 2, 2015	1,090	$ 5.92
Granted during the year	1,155	4.14
Forfeited or expired during the year	(135)	4.69
Vested during the year	(562)	5.29
Unvested at January 1, 2016 (see Note 18)	1,548	$ 4.34

STAAR SURGICAL COMPANY AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The weighted-average grant-date fair value of options granted during the fiscal years ended January 1, 2016, January 2, 2015 and January 3, 2014, were $4.14, $6.81, and $3.51 per option respectively. The total intrinsic value of options exercised during the fiscal years ended January 1, 2016, January 2, 2015, and January 3, 2014, were $2.0 million, $5.5 million, and $3.9 million, respectively.

Warrants

On June 1, 2009, the Company issued warrants to Broadwood Partners, L.P. (“Broadwood”), pursuant to a Warrant Agreement, granting the right to purchase up to an additional 700,000 shares of Common Stock at an exercise price of $4.00 per share. In 2015, the warrants were exercised and as of January 1, 2016 there were no warrants outstanding.

Restricted stock

A summary of restricted stock activity for the year ended January 1, 2016 is presented below:

	Shares (000’s)	Weighted Average Grant-Date Fair Value per Share
Outstanding at January 2, 2015	247	$ 9.41
Granted	34	8.62
Vested	(142)	11.88
Forfeited or expired	(15)	6.26
Outstanding at January 1, 2016 (see Note 18)	124	$ 6.97

Restricted Stock Units

A summary of restricted stock units' activity for the year ended January 1, 2016 is presented below:

	Units (000's)	Weighted Average Grant-Date Fair Value per Share
Outstanding at January 2, 2015	156	$ 15.14
Granted	230	7.60
Vested	(16)	9.20
Forfeited or expired	(31)	15.20
Outstanding at January 1, 2016 (see Note 18)	339	$ 10.44

Note 12 — Commitments and Contingencies

Lease Obligations and Firm Commitment

The Company leases certain property, plant and equipment under capital and operating lease agreements. These leases vary in duration and contain renewal options and/or escalation clauses. Current and long-term obligations under capital leases are included in the Company's consolidated balance sheets.

STAAR SURGICAL COMPANY AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Estimated future minimum lease payments under leases having initial or remaining non-cancelable lease terms in excess of one year as of January 1, 2016 are as follows (in thousands):

Fiscal Year	Operating Leases	Capital Leases
2016	$ 1,657	$ 384
2017	1,340	177
2018	749	31
2019	698	—
2020	648	—
Thereafter	434	—
Total minimum lease payments	$ 5,526	$ 592
Less amounts representing interest	—	26
	$ 5,526	$ 566

Rent expense was approximately $1.2 million, $1.4 million, and $1.5 million, for the years ended January 1, 2016, January 2, 2015 and January 3, 2014, respectively.

The Company had the following assets under capital lease at January 1, 2016 and January 2, 2015 (in thousands):

	2015	2014
Machinery and equipment	$1,195	$1,141
Furniture and fixtures	7	334
Leasehold improvements	—	21
	1,202	1,496
Less accumulated depreciation	329	511
	$873	$985

Depreciation expense for assets under capital lease for each of the years ended January 1, 2016, January 2, 2015, and January 3, 2014, was approximately $176,000, $330,000, and $566,000, respectively.

Indemnification Agreements

The Company has entered into indemnification agreements with its directors and officers that may require the Company: (a) to indemnify them against liabilities that may arise by reason of their status or service as directors or officers, except as prohibited by applicable law; (b) to advance their expenses incurred as a result of any proceeding against them as to which they could be indemnified; and (c) to make a good faith determination whether or not it is practicable for the Company to obtain directors' and officers' insurance. The Company currently has directors' and officers' liability insurance through a third party carrier. Also, in connection with the sale of products and entering into business relationships in the ordinary course of business, the Company may make representations affirming, among other things, that its products do not infringe on the intellectual property rights of others and agrees to indemnify customers against third-party claims for such infringement as well as its negligence. The Company has not been required to make material payments under such provisions.

Tax Filings

The Company's tax filings are subject to audit by taxing authorities in jurisdictions where it conducts business. These audits may result in assessments of additional taxes that are subsequently resolved with the authorities or potentially through the courts. Management believes the Company has adequately provided for taxes; however, final assessments, if any, could be significantly different than the amounts recorded in the consolidated financial statements.

STAAR SURGICAL COMPANY AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Employment Agreements

On October 3, 2014, the Company's former Chief Executive Officer announced his retirement effective March 1, 2015. Effective with his retirement, he became a consultant to the Company through March 31, 2016. In March 2015, the Company accrued approximately $300,000 in benefits due to the former CEO, such benefits are being paid over a one year period beginning on March 1, 2015 and ending on March 31, 2016. As of January 1, 2016, there was approximately $60,000 remaining to be paid to the former CEO pursuant to this agreement through March 31, 2016.

The Company's Chief Executive Officer entered into an employment agreement with the Company, effective March 1, 2015. She and certain officers have as provisions of their agreements certain rights, including continuance of cash compensation and benefits, upon a "change in control," which may include an acquisition of substantially all of its assets, or termination "without cause or for good reason" as defined in the employment agreements.

Litigation and Claims

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 claims. 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.

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 October 20, 2014, plaintiff amended its complaint, dismissed two Company officers, added one other officer, reduced the alleged Class Period to November 1, 2013 through June 30, 2014, and demanded compensatory damages and fees. On September 21, 2015, the Company filed a motion to dismiss the amended complaint. On November 16, 2015, the court issued a tentative ruling rejecting the motion to dismiss. 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 itself against this lawsuit. The Company has not recorded any loss or accrual in the accompanying consolidated financial statements at January 1, 2016 and January 2, 2015 for this matter as the likelihood and amount of loss, if any, has not been determined and is not currently estimable.

Nidek Co., Ltd.

In 2015, Nidek Co., Ltd, wrote to the Company claiming damages related to allegedly defective injectors. The Company is currently investigating the matter and is in discussions with Nidek. The ultimate outcome of this matter cannot be determined with certainty and the Company intends to vigorously protect its interests and work with all parties involved to resolve this matter. The Company has not recorded any loss or accrual in the accompanying consolidated financial statements at January 1, 2016 for this matter as the likelihood and amount of loss, if any, has not been determined and is not currently estimable.

Note 13 — Related Party Transactions

The Company has made various advances to certain non-executive employees. Amounts due from employees included in prepayments, deposits, and other current assets at January 1, 2016 and January 2, 2015 were $20,000 and $9,000, respectively.

STAAR SURGICAL COMPANY AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 14 — Supplemental Disclosure of Cash Flow Information

Interest paid was $121,000, $139,000, and $153,000, for the years ended January 1, 2016, January 2, 2015 and January 3, 2014, respectively. Income taxes paid, net of refunds amounted to approximately $589,000, $1,089,000 and $1,534,000 for the years ended January 1, 2016, January 2, 2015, and January 3, 2014, respectively.

The Company's non-cash investing and financing activities were as follows (in thousands):

Non-cash investing and financing activities:	2015	2014	2013
Assets obtained by capital lease	$ 91	$802	$—
Purchase of property and equipment included in accounts payable	$ 51	$682	$818

Note 15 — Basic and Diluted Net Income (Loss) Per Share

The following table sets forth the computation of basic and diluted net income (loss) per share (in thousands except per share amounts):

	2015	2014	2013
Numerator:			
Net income (loss)	$(6,533)	$(8,392)	$398
Denominator:			
Weighted average common shares and denominator for basic calculation:			
Weighted average common shares outstanding	39,384	38,342	37,017
Less: Unvested restricted stock	(124)	(251)	(311)
Denominator for basic calculation	39,260	38,091	36,706
Weighted average effects of potentially dilutive common stock:			
Stock options	—	—	1,235
Unvested restricted stock	—	—	177

Restricted stock units	—	—	75
Warrants	—	—	414
Denominator for diluted calculation	39,260	38,091	38,607
Net income (loss) per share – basic and diluted	$(0.17)	$(0.22)	$0.01

The following table sets forth (in thousands) the weighted average number of options and warrants to purchase shares of common stock, restricted stock, and restricted stock units which were not included in the calculation of diluted per share amounts because the effects would be anti-dilutive.

	2015	2014	2013
Options	2,506	1,988	1,109
Warrants	345	492	—
Restricted stock and restricted stock units	190	227	—
Total	3,041	2,707	1,109

Note 16 — Geographic and Product Data

The Company markets and sells its products in approximately 60 countries and has manufacturing in the United States. Other than the United States, Japan, Korea, China, and Spain, the Company does not conduct business in any country in which its sales in that country exceed 5% of consolidated sales. Sales are attributed to countries based on location of customers. The composition of the Company's sales to unaffiliated customers is set forth below (in thousands):

STAAR SURGICAL COMPANY AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Net sales to unaffiliated customers	2015	2014	2013
United States	$10,904	$11,117	$12,851
Japan	16,982	19,107	17,666
China	12,571	9,370	8,618
Korea	8,061	6,563	7,743
Spain	5,617	5,562	4,867
Others*	22,988	23,268	20,470
Total	$77,123	$74,987	$72,215

*No other location individually exceeds 5% of total sales.

100% of the Company's sales are generated from the ophthalmic surgical product segment and, therefore, the Company operates as one operating segment for financial reporting purposes. The Company's principal products are IOLs used in cataract surgery and ICLs used in refractive surgery. The composition of the Company's net sales by product line is as follows (in thousands):

Net sales by product line	2015	2014	2013
ICLs	$51,543	$44,047	$44,128
IOLs	19,857	24,336	24,153
Other surgical products	5,723	6,604	3,934
Total	$77,123	$74,987	$72,215

The composition of the Company's long-lived assets, consisting of property and equipment, between those in the United States, Switzerland, and Japan is set forth below (in thousands):

Long-lived assets	2015	2014
U.S.	$9,048	$9,127
Switzerland	672	596
Japan	375	343
Total	$10,095	$10,066

The Company sells its products internationally, which subjects the Company to several potential risks, including fluctuating exchange rates (to the extent the Company's transactions are not in U.S. dollars), regulation of fund transfers by foreign governments, United States and foreign export and import duties and tariffs, and political instability.

Note 17 — Quarterly Financial Data (Unaudited)

Summary unaudited quarterly financial data from continuing operations for fiscal 2015 and 2014 is as follows (in thousands except per share data). The Company has derived this data from the unaudited consolidated interim financial statements that, in the Company's opinion, have been prepared on substantially the same basis as the audited financial statements contained elsewhere in this report and include all normal recurring adjustments necessary for a fair presentation of the financial information for the periods presented. These unaudited quarterly results should be read in conjunction with the financial statements and notes thereto included elsewhere in this report. The operating results in any quarter are not necessarily indicative of the results that may be expected for any future period.

January 1, 2016	1st Qtr.	2nd Qtr.	3rd Qtr.	4th Qtr.
Net sales	$18,858	$18,657	$18,750	$20,858
Gross profit	12,899	12,361	12,799	14,664
Net loss	(2,340)	(1,599)	(1,752)	(842)
Net loss per share – basic and diluted	(0.06)	(0.04)	(0.04)	(0.02)

January 2, 2015	1st Qtr.	2nd Qtr.	3rd Qtr.	4th Qtr.
Net sales	$20,178	$20,048	$18,188	$16,573
Gross profit	13,884	13,667	11,869	9,403
Net loss	(1,359)	(1,789)	(2,706)	(2,538)
Net loss per share – basic and diluted	(0.04)	(0.05)	(0.07)	(0.07)

STAAR SURGICAL COMPANY AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Quarterly and year-to-date computations of net income (loss) per share amounts are made independently. Therefore, the sum of the per share amounts for the quarters may not agree with the per share amounts for the year.

Note 18 — Subsequent Event

On February 11, 2016, one of the Company's shareholders increased its beneficial ownership of the Company's common stock to approximately 26%. This event triggered the "Change in Control" provision in the Company's Amended and Restated 2003 Omnibus Equity Incentive Plan ("Plan"), which resulted in the immediate vesting of all unvested equity awards outstanding under the Plan and the Company recording a $6.9 million non-cash charge to stock-based compensation in the consolidated statements of operations on that date. As of the date of this report, there are approximately 3,654,000 exercisable stock options outstanding and no unvested awards outstanding under the Plan.

STAAR SURGICAL COMPANY AND SUBSIDIARIES

SCHEDULE II — VALUATION AND QUALIFYING ACCOUNTS AND RESERVES

Column A	Column B	Column C	Column D	Column E
Description	**Balance at Beginning of Year**	Additions	Deductions	**Balance at End of Year**
	(In thousands)			
2015				
Allowance for doubtful accounts and sales returns deducted from accounts receivable in balance sheet	$1,589	$ 345	$ 57	$ 1,877
Deferred tax asset valuation allowance	54,104	2,249	3,020	53,333
	$55,693	$ 2,594	$ 3,077	$ 55,210
2014				
Allowance for doubtful accounts and sales returns deducted from accounts receivable in balance sheet	$1,449	$ 384	$ 244	$ 1,589
Deferred tax asset valuation allowance	50,823	3,330	49	54,104
	$52,272	$ 3,714	$ 293	$ 55,693
2013				
Allowance for doubtful accounts and sales returns deducted from accounts receivable in balance sheet	$1,316	$ 263	$ 130	$ 1,449
Deferred tax asset valuation allowance	51,093	744	1,014	50,823
	$52,409	$ 1,007	$ 1,144	$ 52,272