STAAR SURGICAL CO
Form 10-K
March 02, 2017

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K

(Mark One)

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

For the fiscal year ended December 30, 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 ¨ No þ

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant as of July 1, 2016, the last business day of the registrant's most recently completed second fiscal quarter, was approximately $234,602,669 based on the closing price per share of $5.80 of the registrant's Common Stock on that date.

The number of shares outstanding of the registrant's Common Stock as of February 20, 2017 was 40,747,541.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement relating to its 2017 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 manufacturer 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 12. 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 12.

Operations

STAAR has significant operations globally. Activities outside the United States ("U.S.") accounted for 88% of our total sales in fiscal year 2016, primarily due to the pacing of product approvals and commercialization that tend to occur first outside the United States. STAAR sells its products in more than 60 countries, with direct distribution in Japan, the U.S., Spain, Germany, Canada, and the U.K., 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 lens product family, including the EVO Visian ICL (collectively referred to as ICLs), Collamer 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 in Shin-Urayasu and its distribution facility is in Ichikawa City. STAAR performs final packaging of its silicone preloaded IOL injectors and final inspection of its acrylic 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 ICLs used in refractive surgery and IOLs used in cataract 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.

EVO Visian ICL and Visian ICL. Refractive surgery corrects 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 experiences immediate vision improvement within a day.

Our ICL is the only posterior chamber phakic IOL (PIOL) approved by the FDA for marketing and sale in the U.S., and we believe it is the world’s largest selling phakic IOL. Our biocompatible Collamer material belongs to a family of materials known as collagen copolymers. Collagen copolymers are compounds formed by joining molecules of collagen derived from biological sources with synthetic monomer molecules. The proprietary Collamer material is exclusive to us. We believe that the biocompatibility of the Collamer material used for the ICL (and Toric ICL – TICL, which also corrects for astigmatism, as well as the EVO+ Visian ICL, which adds an expanded optical zone to the existing features on the ICL and TICL) is a significant factor in the ability to place this lens safely in the posterior chamber of the eye.

The ICL has been implanted into more than 670,000 eyes worldwide. STAAR began selling the ICL for myopia for use outside the U.S. in 1997. U.S. sales commenced in 2006. In September 2011, STAAR launched the ICL with CentraFLOW technology, which uses a port in the center of the ICL optic in markets outside the U.S. The port is of a

size intended to optimize the flow of fluid within the eye without affecting the quality of vision. The central port also 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 authorized to sell the TICL and the ICL with CentraFLOW technology in the following ex-U.S. regions: the 31 countries that require the European Union CE Mark, China, Canada, Korea, Japan, India, Argentina, 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 the CE Mark for EVO+, an ICL with CentraFLOW technology and an expanded optical zone of 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 ophthalmic surgeons. We are authorized to sell the EVO+ in the following ex-U.S. regions: the 31 countries that require the European Union CE Mark, Korea, Japan, Hong Kong, Turkey, and several countries in the Middle East. The Hyperopic ICL, which treats far-sightedness, is sold primarily in countries that require the European Union CE Mark. Typically, the refractive surgery where an ICL is implanted is an elective procedure paid for or financed by the patient.

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 customer preference for rapid delivery. Outside the U.S., the TICL is available for myopia in the same powers and lengths and carries additional parameters of cylinder and axis. In 2016, approximately 80% of TICL orders were available for shipment in less than one week from receipt. The remaining approximately 20% of TICL orders were custom-made.

According to Market Scope, LLC a publisher of ophthalmic industry data, approximately 3.6 million refractive procedures, primarily laser vision procedures, were performed worldwide in 2016. The incidence of myopia is growing globally, with high myopia becoming more common according to recently published articles (*see*, Ophthalmology, The Journal of the American Academy of Ophthalmology, online publication date June 21, 2016). We believe this will result in a significantly increased number of patients seeking refractive procedures. We believe that over the past decade negative publicity regarding LASIK has reduced patient interest in the LASIK procedure. The ICL is a non-laser based refractive procedure (unlike LASIK) with many ICLs implanted to date. Surgeons have published numerous peer-reviewed articles with clinical data regarding the safety, effectiveness, and visual quality of the ICL. We believe the ICL provides a safe and effective solution for the growing number of myopic patients who will seek visual freedom from eyeglasses and contact lenses.

As part of our sales and marketing efforts, we attend major ophthalmic conventions around the world and invest in market development, practice building, healthcare professional training and patient outreach. We have started working more closely with leading refractive clinics in the area of training, product awareness and practice development. Our marketing programs seek to position the ICL as a premium and primary option for appropriate patients at the clinic and via digital and social media. Last year, we rebranded STAAR as we launched *Evolution in Visual Freedom* websites in our major markets, rolled out new marketing material for surgeons and patients, and introduced our newest ICL, the EVO+. We plan to continue to develop and launch innovative products to support clinical needs and to address the increasing demands of our customers.

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Sales of ICLs (including EVO+ and TICLs) accounted for approximately 72% of our total sales in fiscal 2016, 67% of our total sales in fiscal 2015, and 59% of our total sales in fiscal 2014.

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 small 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 most or all of the cost of cataract surgery and IOLs.

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.

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 24% of our total sales in fiscal 2016, 26% of our total sales in fiscal 2015, and 33% of our total sales in fiscal 2014.

Other Surgical Products

We also sell injector parts to our acrylic lens supplier for their preloaded acrylic IOL that they sell under their own brand. Also, we sell other related instruments and devices that we manufacture, or that are manufactured by others. Generally, these products have lower overall gross profit margins relative to our ICLs and IOLs. Sales of other surgical products accounted for approximately 4% of our total sales in fiscal 2016, 7% of our total sales in fiscal 2015, and 9% of our total sales in fiscal 2014.

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, trademarks, licenses, trade secrets, and copyrights. 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 December 30, 2016, we owned 67 United States and foreign patents and had 20 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 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 product lines.

Worldwide, we sell all our major products under trademarks we consider to be important to our business. STAAR®, EVO Visian ICL™, Evolution in Visual Freedom™, Visian®, Collamer®, CentraFLOW®, AquaPORT®, nanoFLEX® nanoPOINT™, Afinity™, and AquaFLOW™ are trademarks or registered trademarks of STAAR in the U.S. and other countries. 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

While certain individual markets may be impacted by seasonal trends, in the aggregate, seasonality does not materially affect our sales.

Working Capital Requirements

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

Distribution and Customers

We market our products to a variety of health care providers, including ophthalmic surgeons, vision centers, surgical centers, hospitals, government facilities, and distributors. The primary user of our products is an ophthalmologist.

We sell our products directly through our own sales representatives in Japan, the U.S., Spain, Germany, Canada, and the U.K., 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, speakers' programs, digital and 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. Our clinical affairs personnel provide training and educational courses globally.

One customer, Shanghai Langsheng, our China distributor, accounted for more than 19% of our consolidated net sales during fiscal 2016.

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	
2016	$ 16,025	19.4	%
2015	$ 11,851	15.4	%
2014	$ 7,990	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.

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In the refractive market, our ICL technology competes with other elective surgical procedures such as laser vision correction (e.g. 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), Johnson & Johnson (formerly Advanced Medical Optics or AMO), Valeant (formerly Bausch & Lomb or B&L), and Carl Zeiss Meditec AG, all market 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® has been 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 Asia are beginning to appear in the market with their low-cost version of an implantable contact lens, increasing the level of competition.

The global cataract market is highly concentrated, with the top three competitors (Alcon, Abbott Medical Optics, and Bausch & Lomb) combined accounting for approximately 60% of total market revenue, according to a 2016 report by Market Scope.

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 water-based fluid called aqueous humor and is divided, by the iris, into an anterior chamber and a posterior chamber. The cornea is a clear lens at the front of the eye through which light first passes and is focused towards the back of the eye. 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 crystalline lens is located behind the iris that completes the focusing of light and can change shape to focus objects at different distances onto the retina, located in the back of the eye. 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.

Common visual disorders, disease or trauma can affect the eye. 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 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 post-market 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. The FDA deems Class III devices 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.

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 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. Appropriate data must support the IDE application, 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 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 FDA approves the IDE application. 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 manufacturer’s 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 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 because 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.

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.

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 and Switzerland are 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 our principal products sold in CE Mark jurisdictions including ICLs, 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 post-market data gathered within a certain period - normally four years - after approval. The specific post-market reexamination requirement for a medical device is announced at the time of approval.

STAAR Japan currently holds *shonin* approval for the ICL products, 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 Post-market 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 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. In Korea, we provide our distributor with information and data to obtain appropriate registrations and approvals, and the distributor in each country 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. To achieve our business objectives, we will continue our investment in research and development.

Our research and development expenses were approximately $20.3 million, $14.8 million, and $12.4 million for our 2016, 2015, and 2014 fiscal years, respectively. During 2016, our research and development expenses increased $5.5 million as compared to 2015, including increases of $2.7 million in validation and quality assurance related expenses, $1.8 million in clinical activities, $1.0 million in regulatory activities, and $1.3 million in R&D projects, partially offset by a decrease in FDA remediation activities. The Company expects to continue its FDA remediation activities into 2017 and expects to spend approximately $0.5 million for these activities in 2017 as compared to approximately $1.9 million in 2016.

During 2017, 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;

- Development of presbyopia-correcting IOLs; and

- Development of a new generation of ICLs and materials.

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, 2017, we had approximately 336 full-time equivalent employees.

Code of Ethics

STAAR has adopted a revised Code of Business Conduct and Ethics that applies to all 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, marketed with the brand names EVO and EVO+, have 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.

RLE – refractive lens exchange, a refractive surgical procedure in which the natural crystalline lens is removed and replaced with an IOL 9essentially the same as cataract surgery but performed primarily to address refractive issues not to remove a cataract).

refractive market – as used in this report "refractive market" means the overall market volume for refractive surgical procedures of all kinds, including LASIK, PRK, RLE, the 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 four 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. For example, 2017 represents the third year of a three-year transformation designed to increase growth. There can be no guaranty that we will achieve such growth, or profitability, in the near term. 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 identify opportunities to expand our business that require additional financing. Should we need additional working capital, our ability to raise capital 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 economic 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.

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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 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 can 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 might, ultimately, have a material adverse effect on 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 Shanghai Langsheng, which accounted for 19% of our fiscal 2016 consolidated net sales, ceased to serve as our distributor, or significantly underperform our expectations we may experience a substantial reduction 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 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 because 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 any future negative publicity about refractive surgery, the growth of ICL sales could be limited or sales could decline 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, then 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 manufacture the proprietary collagen-based raw material used in our ICLs, IOLs, and the AquaFLOW Device internally. If the supply of these collagen-based raw materials is disrupted it could result in our inability to manufacture those 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. If our suppliers or we are unable or unwilling to meet our manufacturing requirements, we may not be able to produce enough 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 88% of our total sales during 2016. 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 thus changes in exchange rates can make our products more expensive in some offshore markets and reduce our sales. Inflation in emerging markets could also make our products more expensive and increase 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, trade disputes between the United States and its significant trading partners may adversely affect sales.

We may not be able to fully use our recorded tax loss carryforwards.

We have accumulated approximately $136.1 million of U.S. federal tax net operating loss carryforwards as of December 30, 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 2036. 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 expected to be primarily generated outside the U.S. and subject to income taxes, cannot be offset with U.S. loss carryforwards. If profits occur in the U.S. this will enable us to begin using our tax loss carryforwards in the U.S., but unexpected changes in tax laws 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, in Monrovia, CA, if we suffer the partial or total loss of that 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 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. 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 Asia are beginning to appear in some markets with their low-cost version of an implantable contact lens, which competes with our ICL.

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 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 an insurance policy covers a product liability loss, 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 number 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 taken together are underfunded by approximately $4.0 million ($1.2 million for the Japan Plan and $2.8 million for the Swiss Plan) as of December 30, 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 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 could 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, is an important part of our business. Addressing 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. Security breaches could disrupt our operations, and result in 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 whom we do business, may be vulnerable to security breaches, cyber-attacks, or other similar events. Any security breach of Company information, could 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 events could harm our reputation and financial results.

The increased use of social media platforms and mobile technologies presents additional 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.

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.

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, more effective or advanced products could surpass our current and planned products. In addition, we must manufacture these products economically and market them successfully by demonstrating to enough 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 international 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. 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, and to protect or 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. Because 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 because 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 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.

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 and PMA approved 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.

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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, 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 $5.12 to $11.45 per share during the year ended December 30, 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 Certificate of Incorporation and Bylaws, 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 issue one or more series of preferred stock, and to determine the rights of each such series as provided in our Certificate of Incorporation. 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 Certificate of Incorporation and 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. 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.

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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, are in Monrovia, California. STAAR Surgical AG maintains office, manufacturing capabilities, warehouse and distribution facilities in Nidau, Switzerland. The Company leases a research and development facility in Tustin, California and 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 inspection 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 December 30, 2016		
Fourth Quarter	$11.45	$8.20
Third Quarter	9.64	5.61
Second Quarter	7.97	5.12
First Quarter	7.60	6.17
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

Holders

As of February 22, 2017, there were approximately 365 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, 2011 through December 30, 2016 of the total performance of the following:

- STAAR Surgical Company;

- the Nasdaq Stock Market;

- a peer group we have selected consisting of seven 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); and Syneron Medical Ltd. (ELOS). Volcano Corporation (VOLC) and Synergetics USA Inc. (SURG) were previously included in the peer group, but both were acquired and are no longer independent public companies.

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 30, 2011 in STAAR common stock and in each of the composite indices, and that dividends (if any) were reinvested. We have never paid dividends on our common stock and have no present plans to do so.

Total Returns Index for Fiscal Years:	2011	2012	2013	2014	2015	2016
STAAR Surgical Company	100.00	55.48	153.48	86.08	68.06	103.43
The Nasdaq Stock Market (US and Foreign Companies)	100.00	115.20	162.80	187.92	201.40	219.15
Proxy Peer Group	100.00	112.62	153.64	163.55	196.70	244.66

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 12/30/2011.

Item 6. Selected Financial Data

The following table sets forth selected consolidated financial data with respect to the five most recent fiscal years ended December 30, 2016, January 1, 2016, January 2, 2015, January 3, 2014, and December 28, 2012. The selected consolidated statement of operations data set forth below for each of the three most recent fiscal years, and the selected consolidated balance sheet data set forth below at December 30, 2016 and January 1, 2016 are derived from our consolidated financial statements, which have been audited by BDO USA, LLP, our independent registered public accounting firm, as indicated in their report included in this Annual Report. The selected consolidated statement of operations data set forth below for each of the two fiscal years in the periods ended January 3, 2014 and December 28, 2012 and the consolidated balance sheet data set forth below at January 2, 2015, January 3, 2014 and December 28, 2012 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.*"

	December 30, 2016	January 1, 2016	January 2, 2015	January 3, 2014	December 28, 2012
	(In thousands except per share data)				
Statement of Operations					
Net sales	$82,432	$ 77,123	$ 74,987	$ 72,215	$ 63,783
Cost of sales	24,063	24,400	26,164	21,906	19,492
Gross profit	58,369	52,723	48,823	50,309	44,291
General and administrative	22,252	19,604	18,287	16,771	15,150
Marketing and selling	28,478	23,695	25,879	23,888	21,281
Research and development	20,294	14,761	12,363	6,708	6,444
Other general and administrative expenses	—	—	321	2,242	2,636
Operating income (loss)	(12,655)	(5,337)	(8,027)	700	(1,220)
Total other income (expense), net	211	(268)	(618)	414	701
Income (loss) before income taxes	(12,444)	(5,605)	(8,645)	1,114	(519)
Income tax provision (benefit)	(315)	928	(253)	716	1,244
Net income (loss)	$(12,129)	$ (6,533)	$ (8,392)	$ 398	$ (1,763)
Net income (loss) per share – basic and diluted	$(0.30)	$ (0.17)	$ (0.22)	$ 0.01	$ (0.05)
Weighted average shares outstanding-basic	40,329	39,260	38,091	36,706	36,253
Weighted average shares outstanding –diluted	40,329	39,260	38,091	38,607	36,253
Balance Sheet Data					
Working capital	$28,841	$ 31,186	$ 28,526	$ 31,663	$ 26,125
Total assets	65,443	62,954	58,911	61,931	54,759
Long-term obligations	6,471	6,221	5,441	4,667	5,068
Stockholders' equity	37,905	38,846	37,099	38,852	31,742

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 or guidance as to earnings, revenue, sales, profit margins, expense rate, cash, effective tax rate remediation expense or capital expense 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 2017 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 Surgical Company designs, develops, manufactures, and sells implantable lenses for the eye and companion delivery systems used to deliver the lenses into 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 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 ICL family of products, 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 strives for sustainable profitable growth. 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 position our IOL lenses used in surgery that treats cataracts based on quality and value.

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

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

2016 Overview and Strategic Priorities for 2017

In 2016, we devoted significant efforts towards improving our quality system and our remediation efforts. We added several new key employees, particularly in the Research and Development, Clinical and Medical Affairs, and Quality and Operations departments. We finalized nine strategic cooperation agreements with customers intended to enhance future growth. We rebranded STAAR by launching *Evolution in Visual Freedom*™ websites in our major markets and commencing a new marketing campaign that positions the EVO Visian ICL as a premium and primary solution for patients seeking visual freedom from eye glasses and contact lenses. We launched the EVO+, the Visian ICL with CentraFLOW and an expanded optical zone in Europe, and obtained regulatory approval to sell the EVO spheric and EVO toric versions in Canada. We acquired and validated a new Quality Management System and completed a meta-analysis of global peer-reviewed clinical data regarding the ICL, which was published in the peer-reviewed

journal, *Ophthalmology* June 2016. We are in the clinical validation phase of validating an EVO lens with Extended Depth of Field (EDOF).

For 2017, our strategic priorities are as follows:

1. Complete Remediation Plan and Quality Systems Overhaul: We expect to complete our internal remediation and quality system rebuild commitments while also maintaining our global quality certifications;

2. Continue to Build the *Visual Freedom* Market for Implantable Lenses: We will continue our activities to position the ICL as a primary and premium refractive procedure with clinical validation, new digital and social media marketing, product branding launched in 2016, and enhanced surgeon training and practice development programs;

3. Build Go-to-Market Strategy to Expand Market Share Globally: We are planning for double digit ICL growth through a refreshed sales strategy and by entering into additional strategic business relationships with growth-oriented refractive surgical providers operating eye hospitals and clinics;

4. Deliver Global Clinical Validation & Clinical Utility Excellence: The expanded Global Clinical and Medical Affairs teams will continue to assist in supporting submissions to and responding to queries from regulatory agencies and will monitor clinical data, conduct and monitor clinical studies and patient registries established in 2016 and enhance our medical communications protocol; and

5. Innovate, Develop and Release to Market Premium Collamer Lenses and Delivery Systems: We plan to complete research and development efforts relating to EVO (spherical) with EDOF and IOL EDOF lens design and meet internal commitments regarding other research and development priorities.

We expect double-digit ICL unit growth over the next twelve months driven primarily by increasing market acceptance of the EVO Visian ICL in established markets with the exception of the U.S. and Korea. We are working with our Korean distributor to address significant declines in orders anticipated for 2017 as a result of various market and economic conditions in Korea. We anticipate gross profit as a percentage of sales for full year 2017 to be higher than 2016. 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 2017 to be similar to IOL sales in 2016 with the exception of the decrease associated with the discontinuation of the silicone IOL product line in the U.S. Based on the Cataract Care strategy completed in 2016, we are targeting the nanoFLEX Toric IOL for key middle markets and developing a premium IOL on Collamer material with an EDOF optic. We anticipate 2017 total operating expenses may trend above 2016 total operating expenses. We will continue our focus on prudently managing our business, while at the same time striving to fortify the business and prepare for growth. During 2016, we spent approximately $1.9 million on our remediation efforts and expect to spend approximately $0.5 million in 2017.

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, a shareholder 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 the Amended and Restated 2003 Omnibus Equity Incentive Plan ("Plan"). As a result, all unvested equity awards outstanding under the Plan immediately vested. Consequently, we recorded an aggregate $6.9 million non-cash charge to stock-based compensation in the consolidated statements of operations on that date ($4.6 million for stock options and $2.3 million for restricted stock and restricted stock units). This charge was recorded and included in the following categories of the consolidated statements of operations for the year ended December 30, 2016: $2.9 million in general and administrative expenses, $1.5 million in marketing and selling expenses, $1.9 million in research and development expenses and $0.6 million in manufacturing costs. Approximately $3.3 million of the $6.9 million of accelerated charges would have been recognized for stock-based compensation by the Company in fiscal years subsequent to 2016 had the Change in Control provision not been triggered.

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.

	Percentage of Net Sales		
	December 30, 2016	January 1, 2016	January 2, 2015
Net sales	100.0%	100.0%	100.0%
Cost of sales	29.2%	31.6%	34.9%
Gross profit	70.8%	68.4%	65.1%
General and administrative	27.0%	25.4%	24.4%
Marketing and selling	34.5%	30.7%	34.5%
Research and development	24.6%	19.1%	16.5%
Other general and administrative expenses	—%	—%	0.4%
Operating loss	(15.4)%	(6.9)%	(10.7)%
Total other income (expense), net	0.3%	(0.3)%	(0.8)%
Loss before income taxes	(15.1)%	(7.3)%	(11.5)%
Provision (benefit) for income taxes	(0.4)%	1.2%	(0.3)%
Net loss	(14.7)%	(8.5)%	(11.2)%

* 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):

	% of Total	2016	% of Total	2015	% of Total	2014
ICL	71.7 %	$59,111	66.8 %	$51,543	58.7 %	$44,047
IOL	23.9 %	19,706	25.8 %	19,857	32.5 %	24,336
Other	4.4 %	3,615	7.4 %	5,723	8.8 %	6,604
Total Sales	100.0%	$82,432	100.0%	$77,123	100.0%	$74,987

Net sales for 2016 were $82.4 million, a 6.9% increase over the $77.1 million reported in fiscal 2015. The increase in net sales was due to an increase in ICL sales of $7.6 million, partially offset by a $2.3 million decrease in IOLs and other product sales. Changes in foreign currency due to translation of the Japanese yen favorably impacted net sales by $1.5 million, principally affecting IOL sales.

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.

Total ICL sales for 2016 were $59.1 million, a 14.7% increase from $51.5 million reported for fiscal 2015. The sales increase was driven by the APAC region, which grew 18% primarily due to a 35% increase in China sales and a 51% increase in Japan sales, partially offset by an 8% decrease in Korea sales, APAC units grew 16%; the EMEA region grew by 13% primarily due to a 46% increase in Germany sales, in part due to the transition to a direct sales model, EMEA unit sales grew 4%; and the North American region grew by 7% with unit sales flat. Changes in foreign currency favorably impacted ICL sales by approximately $0.3 million. ICL sales represented 71.7% of our total sales for fiscal year 2016.

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 IOL sales were $19.7 million for fiscal 2016, a decrease of 0.8% over the $19.9 million reported in fiscal 2015. Decreased silicone IOL sales in the U.S. due to the discontinuance of the product line, were largely offset by changes in foreign currency which favorably impacted IOL sales by approximately $1.2 million. Worldwide IOL unit sales decreased 6%. IOL sales represented 23.9% of our total sales for fiscal year 2016.

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.

Other product sales for the year ended December 30, 2016 were $3.6 million, a 36.8% decrease compared to the $5.7 million reported for the year ended January 1, 2016. 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. Other product sales represented 4.4% of our total sales for fiscal year 2016.

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.

Gross Profit

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

	2016	2015	2014
Gross Profit	$58,369	$52,723	$48,823
Gross Profit Margin	70.8 %	68.4 %	65.1 %

Gross profit for the year ended December 30, 2016 was $58.4 million, a 10.7% increase compared to the $52.7 million reported for the year ended January 1, 2016. Gross profit margin increased to 70.8% for fiscal year 2016, compared to 68.4% for fiscal year 2015. The increase in gross profit margin is due to an increase in ICL product mix which has higher gross margins than our IOL and Other products, higher average selling prices, and improved ICL unit costs due to manufacturing improvements, partially offset by higher IOL unit costs due to lower production volumes and higher other cost of goods sold.

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 fiscal year 2015, compared to 65.1% for fiscal year 2014. 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.

General and Administrative Expense

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

	2016	2015	2014
General and Administrative Expense	$22,252	$19,604	$18,287
Percentage of Sales	27.0 %	25.4 %	24.4 %

General and administrative expense for the year ended December 30, 2016 was $22.3 million, a 13.5% increase compared to the $19.6 million reported for the year ended January 1, 2016. The increase in general and administrative expense was primarily due to a $2 million increase in stock-based compensation related to the immediate vesting of

all unvested equity awards because of the triggering of the “Change of Control” provisions of the Company’s equity incentive plan during the first quarter of 2016.

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.

Marketing and Selling Expense

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

	2016		2015		2014	
Marketing and Selling Expense	$28,478		$23,695		$25,879	
Percentage of Sales	34.5	%	30.7	%	34.5	%

Marketing and selling expense for the year ended December 30, 2016 was $28.5 million, a 20.2% increase compared to the $23.7 million reported for the year ended January 1, 2016. The increase in marketing and selling expense is due to increased stock-based compensation, advertising, promotional activities, direct selling costs in Germany and trade show expenses, partially offset by decreased U.S. selling expenses.

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.

Research and Development Expense

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

	2016		2015		2014	
Research and Development Expense	$20,294		$14,761		$12,363	
Percentage of Sales	24.6	%	19.1	%	16.5	%

Research and development expense for the year ended December 30, 2016 was $20.3 million, a 37.5% increase compared to the $14.8 million reported for the year ended January 1, 2016. The increase is primarily due to increased compensation (including stock compensation) and consulting expenses related to investments in quality system improvements and clinical activity, and higher R&D project costs, partially offset by lower FDA remediation expenses.

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.

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 Income (Expense), Net

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

	2016	2015	2014
Other Income (Expense), net	$211	$(268)	$(618)
Percentage of Sales	0.3 %	(0.3)%	(0.8)%

Other income for the year ended December 30, 2016 was $0.2 million, compared to the $0.3 million of other expense reported for the year ended January 1, 2016, and $0.6 million of other expense for the year ended January 2, 2015.

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)	
	2016 v. 2015	2015 v. 2014
Interest income	$ (47)	$ (1)
Interest expense	13	26
Exchange losses	802	(53)
Royalty income	(122)	385

Other	(167)	(7)
Net change in other income (expense), net	$ 479	$ 350

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Provision (Benefit) for Income Taxes

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

	2016	2015	2014
Provision (Benefit) for Income Taxes	$(315)	$928	$(253)

The Company recorded a benefit for income taxes in fiscal 2016, primarily due to 1) the Company's net operating losses reported by its foreign operations principally due to the acceleration of stock-based compensation during the first quarter of 2016 and 2) a reduction in its foreign withholding taxes in connection with the dissolution of one of its foreign subsidiaries effective April 1, 2016. There are no unrecognized tax benefits related to uncertain tax positions taken by the Company.

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.

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 2017, and for the foreseeable future, we will be highly dependent on our operating cash flows to supplement our current liquidity and funding of our operations. We may in the future supplement our working capital.

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. Our need for working capital, and the terms on which financing may be available, will depend in part on our degree of success in maintaining positive cash flow through the strategies described above under the caption "*—Overview—*."

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

	2016	2015	2014	2016 v. 2015	2015 v. 2014
Cash and cash equivalents	$14.0	$13.4	$13.0	$ 0.6	$ 0.4
Current assets	$49.9	$49.1	$44.9	$ 0.8	$ 4.2
Current liabilities	21.1	17.9	16.4	3.2	1.5
Working capital	$28.8	$31.2	$28.5	$ (2.4)	$ 2.7

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

Net cash provided by operating activities was $1.0 million for fiscal year 2016 compared to cash used in operating activities of $2.2 million for fiscal year 2015 and cash used in operating activities of $8.0 for fiscal year 2014. For 2016, net cash provided by operating activities consisted of $12.1 million net loss, offset by $11.0 million in non-cash items and $2.1 million in working capital changes. For 2015, net cash used in operating activities consisted of $6.5 million net loss, offset by $6.7 million in non-cash items and $2.3 million in working capital changes.

Net cash used in investing activities was $3.2 million, $2.0 million, and $4.1 million, for fiscal years 2016, 2015, and 2014, respectively, and relate primarily to the acquisition of property, plant, and equipment. The increase in investment in property, plant, and equipment during 2016, relative to 2015, was primarily due to the investments made in connection with manufacturing and quality system improvement projects. The decrease in investment in property, plant, and equipment during 2015, relative to 2014, was primarily due to the investments made in the relocation of all manufacturing to the Company's Monrovia, CA facility which was completed during 2014.

Net cash provided by financing activities was $3.0 million, $4.6 million, and $2.5 million for fiscal years 2016, 2015, and 2014, respectively. For 2016, net cash provided by financing activities consisted of $2.4 million in proceeds from the exercise of stock options, $1.5 million in proceeds from sale leaseback transactions, partially offset by $0.4 million in repayments of capital lease lines of credit and $0.6 million in the repurchase of common stock shares from employees to satisfy minimum tax withholdings. For 2015, net cash provided by financing 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 financing 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 $16.3 million as of December 30, 2016, and $15.7 million as of January 1, 2016. Days' Sales Outstanding (DSO) was 72 days in 2016 and 74 days in 2015.

Inventories at the end of fiscal 2016 and 2015 were $14.8 million and $15.9 million, respectively. Days' Inventory on Hand (DOH) was 216 days in 2016 and 212 days in 2015 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. The shelf registration expires on May 12, 2017, and there has been no decision whether to file a new shelf registration when it expires. 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 several 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, Lease Line of Credit, 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 or about November 21, 2016, with Mizuho Bank which provides for borrowings of up to 500,000,000 Yen, at an interest rate equal to the uncollateralized overnight call rate (approximately 0.12% as of December 30, 2016) plus a 0.50% spread, and may be renewed annually (the current line expires on November 21, 2017). The credit facility is not collateralized. The Company had 500,000,000 Yen outstanding on the line of credit as of December 30, 2016 and January 1, 2016 (approximately $4.3 million and $4.2 million based on the foreign exchange rates on December 30, 2016 and January 1, 2016, 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 December 30, 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 December 30, 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 December 30, 2016 and January 1, 2016.

Covenant Compliance

The Company is in compliance with the covenants of its credit facilities and lines of credit as December 30, 2016.

Lease Line of Credit (Capital Leases)

On June 7, 2016, the Company entered into lease schedule 009 of an existing master lease agreement with Farnam Street Financial, Inc. ("Farnam"). The line of credit provided for borrowings of up to $2.0 million at a lease rate factor

of 3.94% per $1 for hardware equipment and 4.75% per $1 for non-hardware equipment. Interim rent is paid until the full amount of the line is used at which time the lease commences. Approximately $1.5 million of the line was settled through sale-leaseback transactions. As of December 30, 2016, approximately $1,957,000 of the line had been used and $43,000 was available for borrowing. On January 31, 2017, lease 009 was closed and lease 009R commenced. Under 009R, equipment with a cost of $1,957,000 is financed over a period of 24 months at a lease rate factor of 3.94% per $1 for hardware equipment and 4.75% per $1 for non-hardware equipment. At the end of the lease the Company can opt to continue to rent the equipment, return the equipment, or exercise a fair market value purchase option.

On June 12, 2014, the Company entered into lease schedule 008R with Farnam. Under the agreement, hardware and non-hardware with a cost of $964,612 was financed over a period of 36 months at a lease rate factor of 2.81% per $1 for hardware equipment and 3.12% per $1 for non-hardware equipment. At the end of the lease the Company can opt to continue to rent the equipment, return the equipment, or exercise a fair market value purchase option. As of December 30, 2016, approximately $124,705 is outstanding and payable in 2017.

On January 30, 2017, the Company entered into lease schedule 010 with Farnam. The line of credit provides for borrowings of up to $2.0 million at a lease rate factor of 3.94% per $1 for hardware equipment and 4.75% per $1 for non-hardware equipment. Interim rent is paid until the full amount of the line is used at which time the lease commences. There are no material obligations outstanding under lease schedule 010 at this time.

Contractual Obligations

The following table represents the Company's known contractual obligations as of December 30, 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	$4,283	$4,283	$	$	$
Capital lease obligations	2,580	1,220	1,355	5	
Operating lease obligations	5,720	1,849	2,004	1,414	453
Pension benefit payments	1,154	191	217	269	477
Severance	136	136			
Open purchase orders	1,478	1,478			
Total	$15,351	$9,157	$3,576	$1,688	$ 930

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 customer receives the product. 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.

Beginning in 2016, the Company entered into certain strategic cooperation agreements with customers in which, as consideration for minimum purchase commitments the customers make, the Company agrees to pay for marketing and support of Company products. The Company accounts for these arrangements in accordance with ASC 605-50, *Revenue Recognition – Customer Payments and Incentives*. The provisions in these arrangements allow for these payments to be made directly to the customer in lieu of marketing and support or, payments can be made for distinct marketing and support services provided by the customer or another party.

For payments the Company makes to the customer for which no distinct service is provided, the Company records these payments as a reduction of revenues as incurred. For payments the Company makes to another party, or reimburses the customer, for distinct marketing and support services, the Company recognizes these payments as a sales and marketing expense as incurred.

Since the payments for distinct or non-distinct services occur within the quarter corresponding with the purchases made by the customer and the shipments made by the Company to that customer, there is no remaining performance obligation by the Company to the customer. Accordingly, there are no deferred revenues associated with these types of arrangements as of December 30, 2016.

In conjunction with sales to certain customers, the Company provides free products upon attaining certain levels of purchases by the customer. The Company accounts for these free products in accordance with ASC 605-50 *"Revenue Recognition – Customer Payments and Incentives"* and recognizes the cost of the product as part of cost of sales. Free products shipped to the customer are shipped concurrently with the paid products, therefore the Company does not have any undelivered products and no deferred revenues as of December 30, 2016.

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. As of December 30, 2016, the Company has accounts receivable of approximately $400,000 with a former distributor that has been outstanding for more than one year. While the distributor has not disputed the validity of the receivable, it has raised an unrelated matter as the basis for non-payment. The Company believes the receivable is collectible and will commence formal collection action, if necessary. If the Company is unable to collect the outstanding receivable, it would impact the Company's financial results.

- *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 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 11 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 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 can 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 each financial statement period could be impacted if we prevailed in matters for which reserves have been established, or were required to pay amounts more than established reserves.

Inventories. We provide estimated inventory allowances for excess, slow moving, expiring and obsolete inventory as well as inventory whose carrying value is more than 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. If 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 several 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.*

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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. If 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 several 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.

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- *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 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 do not have any off-balance sheet arrangements.

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 December 30, 2016, STAAR had $4.3 million of foreign debt. Our $4.3 million of foreign debt bears an interest rate that is equal to the uncollateralized overnight call rate in Japan (approximately 0.12%) plus a 0.50% spread. Thus, our interest expense would fluctuate with any change in the prime interest rate. If the uncollateralized overnight call rate were to increase or decrease by 1% for the year, our annual interest expense would increase or decrease by approximately $43,000.

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 December 30, 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 year ended December 30, 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 December 30, 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 December 30, 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 December 30, 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 December 30, 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 December 30, 2016 and January 1, 2016, and the related consolidated statements of operations, comprehensive loss, stockholders' equity, and cash flows for each of the three years in the period ended December 30, 2016 and our report dated March 2, 2017 expressed an unqualified opinion thereon.

/s/ BDO USA, LLP

Los Angeles, California

March 2, 2017

Item 9B. Other Information

On June 7, 2016, the Company entered into lease schedule 009 of an existing master lease agreement with Farnam Street Financial, Inc. ("Farnam"). The line of credit provided for borrowings of up to $2.0 million at a lease rate factor of 3.94% per $1 for hardware equipment and 4.75% per $1 for non-hardware equipment. Interim rent is paid until the full amount of the line is used at which time the lease commences. Approximately $1.5 million of the line was settled through sale-leaseback transactions. As of December 30, 2016, approximately $1,957,000 of the line had been used and $43,000 was available for borrowing. On January 31, 2017, lease 009 was closed and lease 009R commenced. Under 009R, equipment with a cost of $1,957,000 is financed over a period of 24 months at a lease rate factor of 3.94% per $1 for hardware equipment and 4.75% per $1 for non-hardware equipment. At the end of the lease the Company can opt to continue to rent the equipment, return the equipment, or exercise a fair market value purchase option.

On January 30, 2017, the Company entered into lease schedule 010 with Farnam Street Financial. The line of credit provides for borrowings of up to $2.0 million at a lease rate factor of 3.94% per $1 for hardware equipment and 4.75% per $1 for non-hardware equipment. Interim rent is paid until the full amount of the line is used at which time the lease term commences. There are no material obligations outstanding under lease schedule 010 at this time.

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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 2017 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 December 30, 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 Accounting 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, Financial Statement Schedules

We have filed the following documents as part of this Annual Report on Form 10-K:

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 STAAR Surgical Company Omnibus Equity Incentive Plan.(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)
†10.31	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 Company and Nidek Co., Ltd., dated March 31, 2016.(23)
†10.34	Employment Agreement effective March 1, 2015 by and between the Company and Caren Mason, dated March 1, 2015. (22)
10.35	Form of Option Grant and Stock Option Agreement for employees.*
10.36	Form of Option Grant and Stock Option Agreement for non-employees directors.*
10.37	Form of Restricted Stock Unit Grant and Agreement.*
10.38	Form of Restricted Stock Award Grant and Restricted Stock Award Agreement.*
10.39	Amendment to Credit Agreement between STAAR Japan Inc. and Mizuho Bank Ltd., dated November 21, 2016.*
10.40	Master Lease Agreement dated May 30, 2006 by and between the Company and Farnam Street Financial, Inc.*
10.41	Lease Schedule No. 008R dated June 12, 2014, of Master Lease Agreement dated May 30, 2006 by and between the Company and Farnam Street Financial, Inc.*
10.42	Lease Schedule No. 009 and Purchase Option dated June 7, 2016, of Lease Agreement dated May 30, 2006, by and between the Company and Farnam Street Financial, Inc.*
10.43	Lease Schedule No. 009R dated January 31, 2017, of Master Lease Agreement dated May 30, 2006, by and between the Company and Farnam Street Financial, Inc.*
10.44	Lease Schedule No. 010 and Purchase Option dated January 30, 2017, of Lease Agreement dated May 30, 2006, by and between the Company and Farnam Street Financial, Inc.*
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 December 30, 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.

*** 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 June 27, 2016.
(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 Appendix 1 of the Company's Proxy Statement on Form DEF 14A, as filed on May 2, 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 1, 2016, as filed on May 11, 2016.
(24) Incorporated by reference to the Company's Quarterly Report on Form 10-Q for the period ended July 1, 2016, as filed on August 3, 2016.

Item 16. Form 10-K Summary

None.

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 2, 2017 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 2, 2017
/s/ Stephen P. Brown Stephen P. Brown	Vice President, Chief Financial Officer (principal accounting and financial officer)	March 2, 2017
/s/ Louis E. Silverman Louis E. Silverman	Chairman of the Board, Director	March 2, 2017
/s/ Stephen C. Farrell Stephen C. Farrell	Director	March 2, 2017
/s/ John C. Moore John C. Moore	Director	March 2, 2017
/s/ William P. Wall William P. Wall	Director	March 2, 2017

STAAR SURGICAL COMPANY AND SUBSIDIARIES

CONSOLIDATED FINANCIAL STATEMENTS

Years Ended December 30, 2016, January 1, 2016, and January 2, 2015

TABLE OF CONTENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Stockholders

STAAR Surgical Company

Monrovia, CA

We have audited the accompanying consolidated balance sheets of STAAR Surgical Company and Subsidiaries (the "Company") as of December 30, 2016 and January 1, 2016 and the related consolidated statements of operations, comprehensive loss, stockholders' equity, and cash flows for each of the three years in the period ended December 30, 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 consolidated financial statements and schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated 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 consolidated 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 consolidated financial position of STAAR Surgical Company and Subsidiaries at December 30, 2016 and January 1, 2016, and the results of their operations and their cash flows for each of the three years in the period ended December 30, 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 December 30, 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) and our report dated March 2, 2017 expressed an unqualified opinion thereon.

/s/ BDO USA, LLP

Los Angeles, California
March 2, 2017

STAAR SURGICAL COMPANY AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

December 30, 2016 and January 1, 2016

	2016	2015
	(In thousands, except par value amounts)	
ASSETS		
Current assets:		
Cash and cash equivalents	$13,999	$13,402
Accounts receivable trade, net	16,344	15,675
Inventories, net	14,825	15,921
Prepayments, deposits, and other current assets	4,349	3,636
Deferred income taxes	391	439
Total current assets	49,908	49,073
Property, plant and equipment, net	11,790	10,095
Intangible assets, net	473	666
Goodwill	1,786	1,786
Deferred income taxes	714	717
Other assets	772	617
Total assets	$65,443	$62,954
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Line of credit	$4,283	$4,159
Accounts payable	8,311	6,691
Deferred income taxes		370
Obligations under capital leases	1,198	362
Other current liabilities	7,275	6,305
Total current liabilities	21,067	17,887
Obligations under capital leases	1,339	204
Deferred income taxes	881	1,888
Asset retirement obligations	195	156
Deferred rent	59	87
Pension liability	3,997	3,886
Total liabilities	27,538	24,108
Commitments and contingencies (Note 12)		
Stockholders' equity:		
Common stock, $0.01 par value; 60,000 shares authorized: 40,732 and 39,887 shares issued and outstanding at December 30, 2016 and January 1, 2016, respectively	407	399
Additional paid-in capital	197,657	187,007

Accumulated other comprehensive loss	(1,050)	(1,580)
Accumulated deficit	(159,109)	(146,980)
Total stockholders' equity	37,905	38,846
Total liabilities and stockholders' equity	$65,443	$62,954

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

STAAR SURGICAL COMPANY AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF OPERATIONS

Years Ended December 30, 2016, January 1, 2016, and January 2, 2015

	2016	2015	2014
	(In thousands, except per share amounts)		
Net sales	$82,432	$77,123	$74,987
Cost of sales	24,063	24,400	26,164
Gross profit	58,369	52,723	48,823
Selling, general and administrative expenses:			
General and administrative	22,252	19,604	18,287
Marketing and selling	28,478	23,695	25,879
Research and development	20,294	14,761	12,363
Other general and administrative expenses	—	—	321
Operating loss	(12,655)	(5,337)	(8,027)
Other income (expense), net:			
Interest income	3	50	51
Interest expense	(115)	(128)	(154)
Loss on foreign currency transactions	(147)	(949)	(896)
Royalty income	618	740	355
Other income (expense), net	(148)	19	26
Other income (expense), net	211	(268)	(618)
Loss before provision (benefit) for income taxes	(12,444)	(5,605)	(8,645)
Provision (benefit) for income taxes	(315)	928	(253)
Net loss	$(12,129)	$(6,533)	$(8,392)
Net loss per share – basic and diluted	$(0.30)	$(0.17)	$(0.22)
Weighted average shares outstanding – basic and diluted	40,329	39,260	38,091

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

STAAR SURGICAL COMPANY AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

Years Ended December 30, 2016, January 1, 2016, and January 2, 2015

	2016	2015	2014
	(In thousands)		
Net loss	$(12,129)	$(6,533)	$(8,392)
Other comprehensive income (loss), net of tax:			
Foreign currency translation adjustment, net of tax	156	31	(955)
Pension liability adjustment, net of tax	374	(541)	(397)
Other comprehensive income (loss)	530	(510)	(1,352)
Comprehensive loss	$(11,599)	$(7,043)	$(9,744)

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

STAAR SURGICAL COMPANY AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

Years Ended December 30, 2016, January 1, 2016, and January 2, 2015

(**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 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
Net loss	—	—	—	—	(12,129)	(12,129)
Other comprehensive income	—	—	—	530	—	530
Common stock issued upon exercise of options	541	5	2,433	—	—	2,438
Stock-based compensation	—	—	8,827	—	—	8,827
Repurchase of employee common stock for taxes withheld	(98)	—	(611)	—	—	(611)
Unvested restricted stock	23	—	—	—	—	—
Vested restricted stock	379	3	1	—	—	4
Balance, at December 30, 2016	40,732	$ 407	$ 197,657	$ (1,050)	$ (159,109)	$ 37,905

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

STAAR SURGICAL COMPANY AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS

Years Ended December 30, 2016, January 1, 2016, and January 2, 2015

	2016	2015	2014
	(In thousands)		
Cash flows from operating activities:			
Net loss	$(12,129)	$(6,533)	$(8,392)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:			
Depreciation of property, plant, and equipment	2,664	2,196	2,078
Amortization of intangibles	228	205	382
Deferred income taxes	(1,364)	473	(841)
Change in net pension liability	491	190	194
Loss on disposal of property and equipment	222	—	—
Stock-based compensation expense	8,558	3,304	4,663
Accretion of asset retirement obligation	—	—	3
Provision for sales returns and bad debts	205	345	182
Changes in working capital:			
Accounts receivable	(771)	(4,952)	(934)
Inventories, net	1,823	327	(3,943)
Prepayments, deposits, and other current assets	(851)	856	(1,062)
Accounts payable	1,007	14	972
Other current liabilities	966	1,413	(1,253)
Net cash provided by (used in) operating activities	1,049	(2,162)	(7,951)
Cash flows from investing activities:			
Acquisition of property and equipment	(3,205)	(2,045)	(4,054)
Sale of property and equipment	—	2	—
Net cash used in investing activities	(3,205)	(2,043)	(4,054)
Cash flows from financing activities:			
Repayment of capital lease obligations	(424)	(391)	(490)
Proceeds from sale-leaseback transactions	1,546	—	—
Repurchase of employee common stock for taxes withheld	(611)	—	—
Proceeds from the exercise of stock options	2,438	2,168	3,022
Proceeds from vested restricted stock	4	2	—
Proceeds from the exercise of warrants	—	2,800	—
Net cash provided by financing activities	2,953	4,579	2,532
Effect of exchange rate changes on cash and cash equivalents	(200)	15	(468)

Increase (decrease) in cash and cash equivalents	597	389	(9,941)
Cash and cash equivalents, at beginning of year	13,402	13,013	22,954
Cash and cash equivalents, at end of year	$13,999	$13,402	$13,013

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 implantable lenses for the eye and delivery systems used to deliver the lenses into the eye. Principal products are implantable Collamer lenses ("ICLs") and intraocular lenses ("IOLs"). ICLs, consisting of the Company's ICL family of products, including the Toric implantable Collamer lenses ("TICL") and EVO+ Visian ICL, are intraocular lenses used to correct refractive conditions such as myopia (near-sightedness), hyperopia (far-sightedness) and astigmatism. 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).

As of December 30, 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.

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 Company 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 years 2016, 2015, and 2014 are based on a 52-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 2016, 2015, and 2014, the net foreign translation gains (losses) were $156,000, $31,000 and $(955,000), respectively, and net foreign currency transaction losses, included in the consolidated statements of operations under other income (expense), net were, $147,000, $949,000, and $896,000, 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 have been transferred, which is typically at shipping point, except for certain customers and for the STAAR Japan subsidiary, which is typically recognized when the customer receives the product. The Company does not have significant deferred revenues as of December 30, 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).

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.

STAAR SURGICAL COMPANY AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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.

Beginning in 2016, the Company entered into certain strategic cooperation agreements with customers in which, as consideration for minimum purchase commitments the customers make, the Company agrees to pay for marketing and support of the Company's products. The Company accounts for these arrangements in accordance with ASC 605-50, *Revenue Recognition – Customer Payments and Incentives*. The provisions in these arrangements allow for these payments to be made directly to the customer in lieu of marketing and support or, payments can be made for distinct marketing and support services provided by the customer or another party.

For payments the Company makes to the customer for which no distinct service is provided, the Company records these payments as a reduction of revenues as incurred. For payments the Company makes to another party, or reimburses the customer, for distinct marketing and support services, the Company recognizes these payments as a sales and marketing expense as incurred.

Since the payments for distinct or non-distinct services occur within the quarter corresponding with the purchases made by the customer and the shipments made by the Company to that customer, there is no remaining performance obligation by the Company to the customer. Accordingly, there are no deferred revenues associated with these types of arrangements as of December 30, 2016.

In conjunction with sales to certain customers, the Company provides free products upon attaining certain levels of purchases by the customer. The Company accounts for these free products in accordance with ASC 605-50 *"Revenue Recognition – Customer Payments and Incentives"* and recognizes the cost of the product as part of cost of sales. Free products shipped to the customer are shipped concurrently with the paid products, therefore the Company does not have any undelivered products and no deferred revenues as of December 30, 2016.

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.

STAAR SURGICAL COMPANY AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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.

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 December 30, 2016, there were two customers with trade receivable balances that represented 10% or more of consolidated trade receivables. As of January 1, 2016, there was one customer with a trade receivable balance 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, taken together, have not exceeded management’s expectations.

There was one customer who accounted for 19% of the Company's consolidated net sales in fiscal 2016, two customers who accounted for 15% and 10% of the Company's consolidated net sales in fiscal 2015, and one customer that accounted for 11% in fiscal 2014.

Fair Value of Financial Instruments

Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. To increase the comparability of fair value measures, the following hierarchy prioritizes the inputs to valuation methodologies used to measure fair value (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
Computers, software, 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 December 30, 2016 and January 1, 2016, 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 December 30, 2016 and January

1, 2016 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 $4.0 million, $2.5 million, and $2.8 million, for fiscal 2016, 2015, and 2014, 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 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.

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.

STAAR SURGICAL COMPANY AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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 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 consolidated statements 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 statements 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).

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 and 15).

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 when the Company concludes that it is probable that the performance condition will be achieved, net of an estimate of pre-vesting forfeitures, over the requisite service period based on the grant-date fair value of the stock. The Company reassesses the probability of vesting at each reporting period and adjusts compensation cost based on its probability assessment.

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

The Company accounts for options granted to persons other than employees and directors under 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 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 December 30, 2016, January 1, 2016, and January 2, 2015 (in thousands):

STAAR SURGICAL COMPANY AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

	Foreign Currency Translation	Defined Benefit Pension Plan-Japan	Defined Benefit Pension Plan-Switzerland	Accumulated Other Comprehensive Income (Loss)
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)
Other comprehensive income (loss)	224	(9)	428	641
Tax effect	(68)	2	(47)	(111)
Balance at December 30, 2016	$ 11	$ 88	$ (1,149)	$ (1,050)

Recent Accounting Pronouncements Not Yet Adopted

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.

In January 2017, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) ASU 2017-04, “Intangibles—Goodwill and Other (Topic 350)” (ASU 2017-04) which simplifies the test for goodwill impairment. ASU 2017-04 is effective for annual or any interim goodwill impairment tests in fiscal years beginning after December 15, 2019. The Company does not expect ASU 2017-04 to have a material effect on the consolidated financial statements.

In December 2016, FASB issued ASU 2016-20, “Technical Corrections and Improvements to Topic 606, Revenue from Contracts with Customers” (“ASU 2016-20”) which amends narrow aspects of accounting standard ASU 2014-09 “Revenue from Contracts with Customers (Topic 606).” ASU-2016-20 is effective for periods after December 15, 2017. The Company is currently evaluating the impact ASU 2016-20 will have on its consolidated financial statements.

In August 2016, the FASB issued ASU 2016-15, “Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments” (“ASU 2016-15”), which clarifies how companies present and classify certain cash receipts and cash payments in the statement of cash flows. ASU 2016-15 is effective for fiscal years beginning after December 15, 2017 and early adoption is permitted. The Company is currently evaluating the impact ASU 2016-15 will have on its consolidated financial statements.

In March 2016, the FASB issued ASU 2016-09, “Compensation—Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting”, which simplifies several aspects of the accounting for share-based payment transactions, including the income tax consequences, forfeitures, classification of awards as either equity or liabilities, and classification of awards on the statement of cash flows. The update is effective for fiscal years beginning after December 15, 2016. The Company is currently evaluating the impact of the adoption of ASU 2016-09 will have on its consolidated financial statements.

In February 2016, the FASB issued ASU 2016-02, “Leases (Topic 842)”, which requires lessees to 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 does not expect the adoption of ASU 2015-17 will have a material impact 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).

In April 2016, the FASB issued ASU 2016-10, “Revenue from Contracts with Customers (Topic 606): Identifying Performance Obligations and Licensing.” The amendments clarify two aspects of Topic 606: (a) identifying performance obligations; and (b) the licensing implementation guidance. The update is effective for annual periods beginning after December 15, 2017 including interim reporting periods therein.

In May 2016, the FASB issued ASU 2016-12, “Revenue from Contracts with Customers (Topic 606): Narrow-Scope Improvements and Practical Expedients” (“ASU 2016-12”). The amendments in ASU 2016-12 provide clarifying guidance in certain narrow areas and add some practical expedients. Specifically, the amendments in this update (1) clarify the objective of the collectability criterion in step 1, and provides additional clarification for when to recognize revenue for a contract that fails step 1, (2) permit an entity, as an accounting policy election, to exclude amounts collected from customers for all sales (and other similar) taxes from the transaction price, (3) specify that the measurement date for noncash consideration is contract inception, and clarifies that the variable consideration guidance applies only to variability resulting from reasons other than the form of the consideration, (4) provide a

practical expedient that permits an entity to reflect the aggregate effect of all modifications that occur before the beginning of the earliest period presented when identifying the satisfied and unsatisfied performance obligations, determining the transaction price, and allocating the transaction price to the satisfied and unsatisfied performance obligations, and (5) clarifies that a completed contract for purposes of transition is a contract for which all (or substantially all) of the revenue was recognized under legacy GAAP before the date of initial application. Further, accounting for elements of a contract that do not affect revenue under legacy GAAP are irrelevant to the assessment of whether a contract is complete. In addition, the amendments permit an entity to apply the modified retrospective transition method either to all contracts or only to contracts that are not completed contracts, and clarifies that an entity that retrospectively applies the guidance in Topic 606 to each prior reporting period is not required to disclose the effect of the accounting change for the period of adoption. However, an entity is still required to disclose the effect of the changes on any prior periods retrospectively adjusted. The effective date and transition requirements for the amendments are the same as the effective date and transition requirements in Topic 606. The guidance is effective for the Company beginning January 1, 2018, although early adoption is permitted beginning January 1, 2017.

The Company has completed an initial assessment of ASU 2014-09, ASU 2016-10, and ASU 2016-12 and will be working on an implementation plan and evaluate the disclosure requirements under the new standards. Based on the work performed to date, the Company does not expect adoption of the new standards to have a material impact on the consolidated financial statements. The Company has not finalized its transition method for adoption.

Note 2 — Accounts Receivable Trade, Net

Accounts receivable trade, net consisted of the following at December 30, 2016 and January 1, 2016 (in thousands):

	2016	2015
Domestic	$1,828	$1,728
Foreign	16,572	15,824
	18,400	17,552
Less allowance for doubtful accounts and sales returns	2,056	1,877
	$16,344	$15,675

STAAR SURGICAL COMPANY AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 3 — Inventories, Net

Inventories, net consisted of the following at December 30, 2016 and January 1, 2016 (in thousands):

	2016	2015
Raw materials and purchased parts	$2,264	$2,317
Work in process	1,924	1,995
Finished goods	14,268	15,058
	18,456	19,370
Less inventory reserves	3,631	3,449
	$14,825	$15,921

Note 4 — Prepayments, Deposits, and Other Current Assets

Prepayments, deposits, and other current assets consisted of the following at December 30, 2016 and January 1, 2016 (in thousands):

	2016	2015
Prepayments and deposits	$1,003	$971
Prepaid insurance	935	874
Income tax receivable	686	597
Consumption tax receivable	573	
Value added tax (VAT) receivable	668	724
Other current assets	484	470
	$4,349	$3,636

Note 5 — Property, Plant and Equipment, Net

Property, plant and equipment, net consisted of the following at December 30, 2016 and January 1, 2016 (in thousands):

	2016	2015
Machinery and equipment	$19,807	$17,094
Furniture and fixtures	8,025	6,980
Leasehold improvements	9,179	8,611
	37,011	32,685
Less accumulated depreciation	25,221	22,590
	$11,790	$10,095

Depreciation expense for the years ended December 30, 2016, January 1, 2016, and January 2, 2015, was approximately $2.7 million, $2.2 million, and $2.1 million, respectively.

Note 6 — Intangible Assets, Net

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

	December 30, 2016			January 1, 2016		
	Gross Carrying Amount	Accumulated Amortization	Net	Gross Carrying Amount	Accumulated Amortization	Net
Amortized intangible assets:						
Patents and licenses	$9,224	$ (8,930)	$294	$9,207	$ (8,891)	$316
Customer relationships	1,343	(1,209)	134	1,305	(1,044)	261
Developed technology	854	(809)	45	829	(740)	89
Total	$11,421	$ (10,948)	$473	$11,341	$ (10,675)	$666

Aggregate amortization expense for intangible assets was $228,000, $205,000, and $382,000, for the years ended December 30, 2016, January 1, 2016, and January 2, 2015, respectively.

STAAR SURGICAL COMPANY AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Future amortization of intangible assets is as follows (in thousands):

Fiscal Year	Amount
2017	$ 228
2018	228
2019	17
Total	$ 473

Note 7 — Other Current Liabilities

Other current liabilities consisted of the following at December 30, 2016 and January 1, 2016 (in thousands):

	2016	2015
Accrued salaries and wages	$2,334	$1,909
Accrued insurance	501	540
Accrued consumption tax	424	157
Accrued income taxes	1,095	217
Accrued bonuses	1,414	2,114
Other [(1)]	1,507	1,368
	$7,275	$6,305

[(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 uncollateralized overnight call rate (approximately 0.12% as of December 30, 2016) plus a 0.50% spread, and may be renewed annually (the current line expires on November 21, 2017). The credit facility is not collateralized. The Company had 500,000,000 Yen outstanding on the line of credit as of December 30, 2016 and January 1, 2016 (approximately $4.3 million and $4.2 million based on the foreign exchange rates on December 30, 2016 and January 1, 2016, 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 December 30, 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 borrowing of up to 1,000,000 CHF (Swiss Francs) ($1.0 million at the rate of exchange on December 30, 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 December 30, 2016 and January 1, 2016.

Lease Line of Credit (Capital Leases)

On June 7, 2016, the Company entered into lease schedule 009 of an existing master lease agreement with Farnam Street Financial, Inc. ("Farnam"). The line of credit provided for borrowings of up to $2.0 million at a lease rate factor of 3.94% per $1 for hardware equipment and 4.75% per $1 for non-hardware equipment. Interim rent is paid until the full amount of the line is used at which time the lease commences. Approximately $1.5 million of the line was settled through sale-leaseback transactions. As of December 30, 2016, approximately $1,957,000 of the line had been used and $43,000 was available for borrowing. On January 31, 2017, lease 009 was closed and lease 009R commenced. Under 009R, equipment with a cost of $1,957,000 is financed over a period of 24 months at a lease rate factor of 3.94% per $1 for hardware equipment and 4.75% per $1 for non-hardware equipment. At the end of the lease the Company can opt to continue to rent the equipment, return the equipment, or exercise a fair market value purchase option.

STAAR SURGICAL COMPANY AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

On June 12, 2014, the Company entered into lease schedule 008R with Farnam. Under the agreement, equipment with a cost of $964,612 was financed over a period of 36 months at a lease rate factor of 2.81% per $1 for hardware equipment and 3.12% per $1 for non-hardware equipment .. At the end of the lease the Company can opt to continue to rent the equipment, return the equipment, or exercise a fair market value purchase option.

On January 30, 2017, the Company entered into lease schedule 010 with Farnam. The line of credit provides for borrowings of up to $2.0 million at a lease rate factor of 3.94% per $1 for hardware equipment and 4.75% per $1 for non-hardware equipment. Interim rent is paid until the full amount of the line is used at which time the lease commences. There are no material obligations outstanding under lease schedule 010 at this time.

Covenant Compliance

The Company is in compliance with covenants of its credit facilities and lines of credit as of December 30, 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 recorded approximately $195,000 and $156,000, representing the fair value of the ARO liability obligation in noncurrent liabilities at December 30, 2016 and January 1, 2016, respectively. The obligation is currently expected to be settled upon expiration of the lease in 2018.

Note 9 — Income Taxes

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

	2016	2015	2014
Current tax provision:			
U.S. federal (benefit)	$—	$—	$3
State	18	12	15
Foreign	1,031	443	570
Total current provision	1,049	455	588
Deferred tax provision (benefit):			
Foreign provision (benefit)	(1,364)	473	(841)
Total deferred provision (benefit)	(1,364)	473	(841)
Provision (benefit) for income taxes	$(315)	$928	$(253)

As of December 30, 2016, the Company had federal net operating loss carryforwards of $136.1 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 2036. In California, the main state from which the Company conducts its domestic operations, the Company has state net operating losses of $32.1 million available to reduce future California income taxes. The California net operating loss carryforwards expire in varying amounts between 2017 and 2036 and, approximately $9.1 million of those net operating loss carryforwards, will expire over the next two years.

The Company had accrued net income taxes receivable of $367,000 and $380,000 at December 30, 2016 and January 1, 2016, 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):

STAAR SURGICAL COMPANY AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

	2016		2015		2014	
Computed provision (benefit) for taxes based on income at statutory rate	34.0 %	$(4,231)	34.0 %	$(1,905)	34.0 %	$(2,939)
Increase (decrease) in taxes resulting from:						
Permanent differences	(3.0)	373	(0.6)	33	(0.2)	20
Federal minimum taxes	—	—	—	—	(0.1)	3
State minimum taxes, net of federal income tax benefit	(0.1)	12	(0.1)	8	(0.1)	10
State tax benefit	6.2	(767)	(6.6)	370	4.6	(394)
Tax rate difference due to foreign statutory rate	(8.9)	1,109	1.6	(90)	3.3	(288)
Expiration of state net operating tax carryforwards	(7.2)	892	(47.3)	2,650	—	—
Foreign earnings not permanently reinvested	6.5	(809)	(9.8)	547	0.1	(11)
Foreign dividend withholding	3.8	(478)	(3.8)	211	(1.5)	132
Expiration of charitable contribution carryover	(0.1)	12	(0.3)	15	(0.2)	18
Other	1.2	(151)	2.5	(140)	1.0	(85)
Valuation allowance	(29.9)	3,723	13.8	(771)	(38.0)	3,281
Effective tax provision (benefit) rate	2.5 %	$(315)	(16.6)%	$928	2.9 %	$(253)

The Company recorded an income tax benefit of $315,000 during the fiscal year 2016 due to losses generated in its foreign operations and a reduction in foreign withholding taxes in connection with the dissolution of one of its foreign subsidiaries. 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 $253,000 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, about 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 informed by the STA during 2014 that it had met the special ruling qualifications for 2014.

Included in the state tax provision is a decrease to the state deferred tax asset and corresponding decrease to the valuation allowance of $125,000 and $3,020,000, for 2016 and 2015 respectively, 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.

Included in the foreign deferred tax benefit for 2016 is a decrease in foreign deferred liabilities of $617,000. For 2015, there was an increase in foreign deferred liabilities of $172,000. For 2014, there was a decrease in foreign deferred liabilities of $1,039,000.

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 2016, 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 December 30, 2016 and January 1, 2016 are as follows (in thousands):

STAAR SURGICAL COMPANY AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

	2016	2015
Current deferred tax assets (liabilities):		
Allowance for doubtful accounts and sales returns	$245	$90
Inventories	662	422
Accrued vacation	437	382
Accrued other expenses	596	176
Other	66	57
Valuation allowance	(1,615)	(1,058)
Total current deferred tax assets (liabilities)	$391	$69
Non-current deferred tax assets (liabilities):		
Net operating loss carryforwards	$52,843	$51,005
Stock-based compensation	2,154	1,763
Business, foreign and AMT credit carryforwards	1,665	1,730
Capitalized R&D	249	134
Contributions	10	17
Pensions	625	583
Depreciation and amortization	1,060	695
Foreign tax withholding	(881)	(1,627)
Foreign earnings not permanently reinvested	(2,468)	(3,209)
Other	18	13
Valuation allowance	(55,442)	(52,275)
Total non-current deferred tax liabilities	$(167)	$(1,171)

As of December 30, 2016, the Company had net deferred tax liabilities in Switzerland of $473,000 (which included $881,000 of withholding taxes on unremitted foreign earnings) and net deferred tax assets of $698,000 in Japan included in the Company's components of deferred income tax assets and liabilities table. 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.

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. 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 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 December 30, 2016 and 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 $407,000 and $312,000 as of December 30, 2016 and January 1, 2016, respectively.

STAAR SURGICAL COMPANY AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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 noncurrent deferred tax assets of $307,000 (as translated using the Japanese Yen exchange rate on December 30, 2016) and $145,000 as of December 30, 2016 and January 1, 2016, respectively.

Other Income Tax Disclosures

The following tax years remain subject to examination:

Significant Jurisdictions	**Open Years**
U.S. Federal	2013 – 2015
California	2012 – 2015
Switzerland	2015
Japan	2013 – 2015

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

	2016	2015	2014
Domestic	$(10,399)	$(7,678)	$(8,113)
Foreign	(2,045)	2,073	(532)
	$(12,444)	$(5,605)	$(8,645)

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.

Defined Benefit Plan-Switzerland

In Switzerland employers are required to provide a minimum pension plan for their staff. Contributions of both the employees and employer finance the Swiss Plan. 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.

The following table shows the changes in the benefit obligation and plan assets and the Swiss Plan’s funded status as of December 30, 2016 and January 1, 2016 (in thousands):

STAAR SURGICAL COMPANY AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

	2016	2015
Change in Projected Benefit Obligation:		
Projected benefit obligation, beginning of period	$6,349	$4,827
Service cost	469	316
Interest cost	65	74
Participant contributions	230	209
Benefits deposited (paid)	(340)	340
Actuarial (gain) loss	(410)	656
Prior service cost	—	(73)
Projected benefit obligation, end of period	$6,363	$6,349
Change in Plan Assets:		
Plan assets at fair value, beginning of period	$3,498	$2,705
Actual return on plan assets (including foreign currency impact)	(13)	35
Employer contributions	230	209
Participant contributions	230	209
Benefits deposited (paid)	(340)	340
Plan assets at fair value, end of period	$3,606	$3,498
Funded status (pension liability), end of year	$(2,757)	$(2,851)
Amount Recognized in Accumulated Other Comprehensive Loss, net of tax:		
Actuarial loss on plan assets	$(822)	$(822)
Actuarial loss on benefit obligation	(1,393)	(1,668)
Actuarial gain recognized in current year	454	362
Effect of curtailments	606	606
Accumulated other comprehensive loss	$(1,155)	$(1,522)
Accumulated benefit obligation at end of year	$(5,980)	$(5,932)

The underfunded balance of $2.8 million and $2.9 million was included in other long-term liabilities (pension liability) on the consolidated balance sheets as of December 30, 2016 and January 1, 2016, respectively.

Net periodic pension cost associated with the Swiss Plan during the years ended December 30, 2016, January 1, 2016 and January 2, 2015 include the following components (in thousands):

	2016	2015	2014
Service cost	$469	$316	$297

Interest cost	65	74	114
Expected return on plan assets	(89)	(93)	(97)
Actuarial loss recognized in current year	104	64	24
Net periodic pension cost	$549	$361	$338

Changes in other comprehensive income (loss), net of tax, associated with the Swiss Plan in the year ended December 30, 2016, January 1, 2016 and January 2, 2015 include the following components (in thousands):

	2016	2015	2014
Current year actuarial gain (loss) on plan assets, net of tax	$(8)	$(61)	$(375)
Current year actuarial loss on benefit obligation, net of tax	(275)	(635)	(846)
Actuarial gain (loss) recorded in current year, net of tax	(98)	57	28
Effect of curtailments	—	—	782
Change in other comprehensive loss	$(381)	$(517)	$(411)

The amount in accumulated other comprehensive loss as of December 30, 2016 that is expected to be recognized as a component of the net periodic pension costs during fiscal year 2017 is $73,000.

STAAR SURGICAL COMPANY AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Net periodic pension cost and projected and accumulated pension obligation for the Company's Swiss Plan were calculated on December 30, 2016 and January 1, 2016 using the following assumptions:

	2016	2015
Discount rate	0.8 %	1.0 %
Salary increases	2.0 %	2.0 %
Expected return on plan assets	2.5 %	2.5 %
Expected average remaining working lives in years	10.0	10.4

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. To determine an appropriate discount rate, the eight-year rate of return was then extrapolated along the yield curve of Swiss government bonds.

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 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 $3.6 million and $3.5 million as of December 30, 2016 and January 1, 2016, respectively.

The table below sets forth the fair value of Plan assets at December 30, 2016 and January 1, 2016, and the related activity in fiscal years 2015 and 2016, in accordance with ASC 715-20-50-1(d) (in thousands):

	Insurance Contracts (Level 3)
Beginning 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
Actual return on plan assets	(12)
Purchases, sales, and settlement	119
Ending balance at December 30, 2016	$ 3,605

STAAR SURGICAL COMPANY AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

During fiscal 2017, the Company expects to make cash contributions totaling approximately $238,000 to the Swiss Plan.

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

Fiscal Year	Amount
2017	$ 52
2018	56
2019	59
2020	57
2021	62
Thereafter	410
Total	$ 696

Defined Benefit Plan-Japan

STAAR Japan maintains a noncontributory defined benefit pension plan (“Japan Plan”) substantially covering all 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 December 30, 2016 and January 1, 2016 is as follows (in thousands):

	2016	2015
Change in Projected Benefit Obligation:		
Projected benefit obligation, beginning of period	$1,035	$957
Service cost	148	121
Interest cost	6	6
Actuarial gain	49	32
Benefits paid	(17)	(83)
Foreign exchange adjustment	19	2
Projected benefit obligation, end of period	$1,240	$1,035
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	$(1,240)	$(1,035)
Amount Recognized in Accumulated Other Comprehensive Income, Net of Tax:		
Transition obligation	$(14)	$(20)
Actuarial gain (loss)	(31)	122
Prior service cost	8	9
Net gain (loss)	125	(10)
Accumulated other comprehensive income	$88	$101
Accumulated benefit obligation at end of year	$(1,078)	$(893)

STAAR SURGICAL COMPANY AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The underfunded balance of $1,240,000 and $1,035,000, respectively, was included in other long-term liabilities (pension liability) on the consolidated balance sheets as of December 30, 2016 and January 1, 2016.

Net periodic pension cost associated with the Japan Plan for the years ended December 30, 2016, January 1, 2016 and January 2, 2015 includes the following components (in thousands):

	2016	2015	2014
Service cost	$148	$121	$157
Interest cost	6	6	9
Net amortization of transition obligation	12	11	12
Actuarial loss	(13)	(15)	(10)
Prior service credit	(1)	(2)	(1)
Net periodic pension cost	$152	$121	$167

Changes in other comprehensive income (loss), net of tax, associated with the Japan Plan for the years ended December 30, 2016, January 1, 2016 and January 2, 2015 include the following components (in thousands):

	2016	2015	2014
Amortization of net transition obligation	$8	$7	$12
Amortization of actuarial gain (loss)	25	(21)	(9)
Actuarial income (loss) recorded in current year	(40)	(10)	13
Amortization prior service cost	—	—	(2)
Change in other comprehensive income (loss)	$(7)	$(24)	$14

The amount in accumulated other comprehensive loss as of December 30, 2016 that is expected to be recognized as a component of the net periodic pension cost in fiscal 2017 is approximately $7,300.

Net periodic pension cost and projected and accumulated pension obligation for the Company’s Japan Plan were calculated on December 30, 2016 and January 1, 2016 using the following assumptions:

	2016	2015
Discount rate	0.3 %	0.5 %
Salary increases	6.0 %	6.1 %
Expected return on plan assets	N/A	N/A
Expected average remaining working lives in years	8.84	8.13

The discount rate of 0.30% as of December 30, 2016 and the discount rate of 0.50% as of January 1, 2016 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
2017	$ 139
2018	50
2019	52
2020	55
2021	95
Thereafter	67
Total	$ 458

STAAR SURGICAL COMPANY AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Defined Contribution Plan

The Company has a 401(k) profit sharing plan ("401(k) Plan") for the benefit of qualified employees in the U.S. During the fiscal year ended December 30, 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's 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 December 30, 2016, January 1, 2016, and January 2, 2015, the Company made contributions, net of forfeitures, of $703,000, $625,000, and $518,000, respectively, to the 401(k) Plan.

Note 11 — Stockholders' Equity

Immediate Vesting of All Unvested Equity Awards

On February 11, 2016, a shareholder 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 the Amended and Restated 2003 Omnibus Equity Incentive Plan ("Plan"). As a result, all unvested equity awards outstanding under the Plan immediately vested. Consequently, we recorded an aggregate $6.9 million non-cash charge to stock-based compensation in the consolidated statements of operations on that date ($4.6 million for stock options and $2.3 million for restricted stock and restricted stock units). This charge was recorded and included in the following categories of the consolidated statements of operations for the year ended December 30, 2016: $2.9 million in general and administrative expenses, $1.5 million in marketing and selling expenses, $1.9 million in research and development expenses and $0.6 million in manufacturing costs. Approximately $3.3 million of the $6.9 million of accelerated charges would have been recognized for stock-based compensation by the Company in fiscal years subsequent to 2016 had the Change in Control provision not been triggered.

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).

The following table represents the fair value of stock compensation granted during the year ended December 30, 2016:

	Fair Value
Stock Options	$ 2,946
Restricted Stock Units	2,396
Restricted Stock	150
	$ 5,492

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

	Fiscal Year Ended December 30, 2016	January 1, 2016	January 2, 2015
Employee stock options	$5,485	$ 2,306	$ 2,842
Restricted stock	298	485	935
Restricted stock units	2,717	452	795
Consultant compensation	58	61	91
Total	$8,558	$ 3,304	$ 4,663

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

STAAR SURGICAL COMPANY AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

	Fiscal Year Ended		
	December 30, 2016	January 1, 2016	January 2, 2015
Cost of Sales	$612	$52	$108
General and administrative	3,809	2,090	2,552
Marketing and selling	1,961		