

UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 10-K

(Mark One)

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

For the fiscal year ended December 29, 2017

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

(State or other jurisdiction of
incorporation or organization)

95-3797439

(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)

Common Stock, \$0.01 par value

(Name of each exchange on which registered)

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

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

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 No

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

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

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

Large accelerated filer Accelerated filer
Non-accelerated filer (Do not check if smaller reporting company) Smaller reporting company
Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant as of June 30, 2017, the last business day of the registrant's most recently completed second fiscal quarter, was approximately \$443,974,781 based on the closing price per share of \$10.80 of the registrant's Common Stock on that date.

The number of shares outstanding of the registrant's Common Stock as of February 20, 2018 was 41,417,937.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement relating to its 2018 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 or financial performance. STAAR Surgical Company cautions investors and prospective investors that any such forward-looking statements are not guarantees of future performance and involve risks and uncertainties, and that actual results may differ materially from those projected in the forward-looking statements. 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 6.

Operations

STAAR has significant operations globally. Activities outside the United States (U.S.) accounted for 91% of our total sales in fiscal year 2017, 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 75 countries, with direct distribution (i.e., via STAAR representatives) in Japan, the U.S., Spain, Germany, Canada, the U.K. and Singapore, with a combination of direct distribution and independent distribution (i.e., via distributors and STAAR representatives) in China, Korea and India, and with 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) 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.
- *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 product line 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 750,000 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 ICL with CentraFLOW technology and the Toric (TICL), which also corrects for astigmatism, 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, India, Canada, 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, ICL surgery 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.

According to Market Scope, LLC a publisher of ophthalmic industry data, approximately 3.7 million refractive procedures, primarily laser vision procedures, were performed worldwide in 2017. The incidence of myopia is growing globally, with high myopia becoming more common according to recently published articles, affecting nearly 5 billion and 1 billion people, respectively, by 2050 (Global Prevalence of Myopia and High Myopia and Temporal Trends from 2000 through 2050, *Ophthalmology*, Vol. 123, No. 5, May 2016; Global trends in myopia management attitudes and strategies in clinical practice, *Contact Lens and anterior Eye*, Vol. 39, 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 over 750,000 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. In 2016, 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. In October 2017, our European Regulatory Notified Body concluded that STAAR may expand the age range for the EVO Visian family of ICLs indicated for the correction/reduction of myopia from adults aged 21 to 45 to adults aged 21 to 60. In January 2018, our European Regulatory Notified Body authorized a change to Directions for Use of the myopic EVO Visian family lowering the minimum anterior chamber depth (ACD) from 3.0 mm. to 2.8 mm, further increasing the addressable market for the product family. These changes relate to EVO products marketed and sold in CE Mark countries (EU/EEA/EFTA) and in countries that permit regulatory market access based on the CE Mark only regulatory approval for marketing. In December 2017, the EVO+ was approved for marketing and sales in India and Canada. In 2018 we will commence a multi-site clinical trial to support CE Mark approval of a claim that our EVO+ Visian ICL with aspheric (EDOF) optic for the correction/reduction of presbyopia in patients who wish to improve their uncorrected distance, intermediate and near visual acuity with increased spectacle independence.

Sales of ICLs (including EVO+ and TICLs) accounted for approximately 75% of our total sales in fiscal 2017, 72% of our total sales in fiscal 2016 and 67% of our total sales in fiscal 2015.

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 the Collamer material in two differently configured styles: the single-piece design where both the optic and haptics are made of Collamer and the three-piece design where Polyimide loop haptics are attached to the Collamer 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. In addition, STAAR offers silicone in a three-piece design with Polyimide haptics attached to the optic. 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 19% of our total sales in fiscal 2017, 24% of our total sales in fiscal 2016 and 26% of our total sales in fiscal 2015.

Other Surgical Products

We 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 6% of our total sales in fiscal 2017, 4% of our total sales in fiscal 2016 and 7% of our total sales in fiscal 2015.

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 related and important to our business. As of December 29, 2017, we owned approximately 70 United States and foreign patents and had 44 patent applications pending. We rely more on trade secrets than patents and 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 of 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® and Afinity® 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, the U.K. and Singapore. We sell through a combination of our own representatives and independent distributors in China, Korea and India. We sell through independent distributors in other countries. Our products are sold in more than 75 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 26% of our consolidated net sales during fiscal 2017. 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
2017	\$ 23,881	26.4%
2016	\$ 16,025	19.4%
2015	\$ 11,851	15.4%

Backlog

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

Government Contracts

No material portion of our business is subject to renegotiation of profits or termination of any particular contract or subcontract at the election of the U.S. Government.

Competition

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

In the refractive market, our ICL technology competes with other elective surgical procedures such as laser vision correction (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 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 Johnson & Johnson 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. In addition, competitors from Asia are beginning to appear in the market with their low-cost version of a posterior chamber implantable contact lens, increasing the level of competition.

The global cataract market is highly concentrated, with the top three competitors (Novartis, Johnson & Johnson and Valeant) combined accounting for approximately 60% of total market revenue, according to a 2017 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 that causes light to not focus at a single depth in the eye resulting 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 United States 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 and ICLs 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 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 and we submitted additional data in response. On March 14, 2014 an FDA Ophthalmic Devices Panel of the Medical Devices Advisory Committee (Advisory Panel) assessed our PMA Supplement submission seeking approval of the TICL. The Advisory Panel 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 implemented its corrective action plans relating to the 2014 Warning Letter and the 2015 FDA-483. STAAR submitted monthly updates to FDA regarding its progress on corrective actions. In the first quarter of 2017 we notified the FDA that we had completed our remediation work and were ready for inspection. 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, state and international 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 the federal government, the states and the international jurisdictions 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 and international 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 and international 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 and international 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 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 and injector systems. In July 2017, our Notified Body in the European Union, DEKRA, audited our facilities then re-certified our facilities as compliant with ISO 13485, the quality standard applicable for medical devices, and re-certified the CE marking for all our currently certified and commercially available medical devices. In November 2017, DEKRA performed an unannounced audit and concluded that we remained in compliance.

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. In January 2018, the MFDS audited our facilities then concluded we met the regulatory requirements and were in compliance with the current Korean quality system standards, and therefore would recommend renewal of our medical device license.

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 \$19.1 million, \$20.3 million and \$14.8 million for our 2017, 2016 and 2015 fiscal years, respectively. During 2017, our research and development expenses decreased \$1.2 million as compared to 2016 due mainly to a decrease in FDA remediation activities. 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 spent \$0.2 million for FDA remediation activities in 2017 compared to \$1.9 million in 2016.

During 2018, we intend to continue our focus on research and development in the following areas:

- Development of presbyopia-correcting ophthalmic lenses, including models that also correct sphere and cylinder, including clinical trials of the version that corrects presbyopia and sphere;
- Development of preloaded injector systems for ophthalmic lenses; and
- Development of a new generation of ophthalmic lenses 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 December 29, 2017, we had approximately 353 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. An adult with moderate to high 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 ablate tissue 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 - an 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 (essentially 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.

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 aluminum 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. 2017 represented the third year of a three-year transformation designed to increase growth. There can be no guaranty that we will achieve 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.

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 the FDA determines we resolved its concerns. On May 21, 2014, we received the 2014 Warning Letter from the FDA citing alleged violations of cGMP requirements of the 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 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 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 responded in a timely manner to the 2014 Warning Letter and the 2015 FDA-483 and updated the FDA monthly on our corrective actions. In the first quarter of 2017 we notified the FDA that we had completed our remediation work and were ready for inspection. We do not know when the FDA will re-inspect our Monrovia facility. 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 devote significant resources and attention to our quality systems and compliance with QSR and other regulatory requirements for the foreseeable future as part of the ordinary course of business. 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, the U.K. and Singapore, 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 more than 26% of our fiscal 2017 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.

Approximately seventy-five (75%) of our revenue is derived from refractive procedures. 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 and IOLs 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 91% of our total sales during 2017. 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. The strengthening of the U.S. dollar would likely negatively impact our results. 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. Also, we are exposed to credit and collectability risk on our trade receivables with customers in certain international markets. There can be no assurance we can effectively limit our credit risk and avoid losses and our ability to transfer foreign earnings to the U.S. may be subject to taxes or restricted or result in incurring substantial costs.

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

We have accumulated approximately \$132.5 million of U.S. federal tax net operating loss carryforwards as of December 29, 2017, 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 2037. 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, which 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 changes in tax laws could prevent or hinder us from realizing the full 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 and low-cost Asian manufacturers.

Our competitors, including Novartis (formerly Alcon), Johnson & Johnson (formerly Abbott 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, 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 \$4.7 million (\$1.4 million for the Japan Plan and \$3.3 million for the Swiss Plan) as of December 29, 2017.

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. These regulations may 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, local and international 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 or other regulatory bodies. If we determine that certain actions do not require notification of the FDA or others, the FDA or other regulatory bodies 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 or other regulatory bodies 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 or other regulatory bodies 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 or to other regulatory bodies pursuant to international 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 and similar regulations; however, there can be no assurance that the FDA or other regulatory bodies will agree with our decisions. If we fail to report MDRs to the FDA or other regulatory bodies within the required timeframes, or at all, or if the FDA or others disagree with any of our determinations regarding the reportability of certain events, the FDA or other regulatory bodies 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.

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 \$9.10 to \$17.40 per share during the year ended December 29, 2017. 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 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.

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. Our investors recommended three of our current five directors. The sale of a substantial number of our shares by any of our largest investors 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, including 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 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 requirements. The Company could increase capacity in our Monrovia, California facility or elsewhere.

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 29, 2017		
Fourth Quarter	\$ 17.40	\$ 12.45
Third Quarter	12.80	9.90
Second Quarter	10.90	9.10
First Quarter	10.85	9.30
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

Holdings

As of February 21, 2018, there were approximately 342 record holders of our Common Stock.

Dividends

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

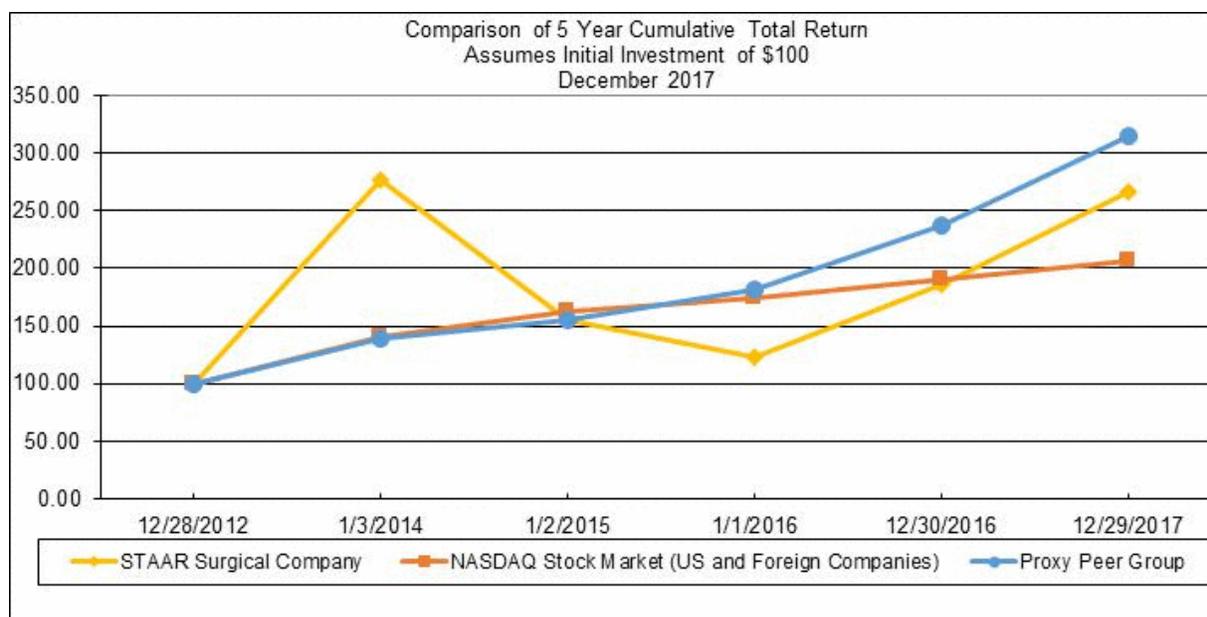
Stock Performance Graph

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

The following graph shows a comparison from December 28, 2012 through December 29, 2017 of the total performance of the following:

- STAAR Surgical Company;
- the Nasdaq Stock Market;
- a peer group we have selected consisting of five companies within our industry or closely related industries: Anika Therapeutics (ANIK); Cutera Inc. (CUTR); Integra LifeSciences Holdings Corp. (IART); Iridex Corp. (IRIX); and Merit Medical Systems, Inc. (MMSI). Cynosure Inc. (CYNO), Volcano Corporation (VOLC), Synergetics USA Inc. (SURG) and Syneron Medical Ltd. (ELOS) were previously included in the peer group, but 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 28, 2012 in STAAR common stock and in each of the composite indices, and that dividends (if any) were reinvested. We have never paid dividends on our common stock and have no present plans to do so.



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Total Returns Index for Fiscal Years:	2012	2013	2014	2015	2016	2017
STAAR Surgical Company	100.00	276.63	155.15	122.68	186.43	266.33
The Nasdaq Stock Market (US and Foreign Companies)	100.00	141.33	161.13	174.83	190.21	206.25
Proxy Peer Group	100.00	139.28	155.06	181.24	237.21	314.67

Notes:

- The lines represent monthly index levels derived from compounded daily returns that include all dividends.
- These indexes are reweighted daily, using the market capitalization from the previous trading day.
- If the monthly interval, based on the fiscal year-end, is not a trading day, the preceding trading day is used.
- The index level for all series was set to \$100.00 on 12/28/2012.

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 29, 2017, December 30, 2016, January 1, 2016, January 2, 2015 and January 3, 2014. 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 29, 2017 and December 30, 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 2, 2015 and January 3, 2014 and the consolidated balance sheet data set forth below at January 1, 2016, January 2, 2015 and January 3, 2014 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 29, 2017	December 30, 2016	January 1, 2016	January 2, 2015	January 3, 2014
(In thousands except per share data)					
Statement of Operations					
Net sales	\$ 90,611	\$ 82,432	\$ 77,123	\$ 74,987	\$ 72,215
Cost of sales	26,331	24,063	24,400	26,164	21,906
Gross profit	64,280	58,369	52,723	48,823	50,309
General and administrative	20,665	22,252	19,604	18,287	16,771
Marketing and selling	28,130	28,478	23,695	25,879	23,888
Research and development	19,116	20,294	14,761	12,363	6,708
Other general and administrative expenses	—	—	—	321	2,242
Operating income (loss)	(3,631)	(12,655)	(5,337)	(8,027)	700
Total other income (expense), net	1,335	211	(268)	(618)	414
Income (loss) before income taxes	(2,296)	(12,444)	(5,605)	(8,645)	1,114
Income tax provision (benefit)	(157)	(315)	928	(253)	716
Net income (loss)	\$ (2,139)	\$ (12,129)	\$ (6,533)	\$ (8,392)	\$ 398
Net income (loss) per share – basic and diluted	\$ (0.05)	\$ (0.30)	\$ (0.17)	\$ (0.22)	\$ 0.01
Weighted average shares outstanding-basic	41,004	40,329	39,260	38,091	36,706
Weighted average shares outstanding –diluted	41,004	40,329	39,260	38,091	38,607
Balance Sheet Data					
Working capital	\$ 34,802	\$ 28,450	\$ 31,117	\$ 28,231	\$ 32,029
Total assets	67,932	65,477	62,400	58,291	61,221
Long-term obligations	5,908	6,505	6,037	5,122	4,696
Stockholders’ equity	42,936	37,905	38,846	37,099	38,852

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 2018 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 Customers
- Competition
- Regulatory Matters
- Research and Development

Strategic Priorities for 2018

For 2018, our strategic priorities are as follows:

- Achieve and Retain Compliance with All Regulatory Bodies;
- Successfully Build the *Visual Freedom* Market for Implantable Lenses;
- Execute Go-to-Market Strategy to Significantly Expand Market Share Globally;
- Innovate, Develop and Introduce Premium Collamer Lenses and Delivery Systems;
- Enhance Clinical & Medical Affairs Excellence: Clinical Validation, Surgeon Training;
- Implement *Foundations 2020*: Operations & Systems Updates & Improvements; and
- Deliver Shareholder Value

In 2018, we expect double-digit revenue growth resulting in greater than \$100 million in revenue in fiscal 2018, ICL sales and unit growth in the mid-teens or greater range, positive cash flow and cash balance improvement as compared with 2017, improved EPS results from 2017, low double-digit increase from 2017 in spending to support commercial infrastructure expansion, clinical studies, including our European EVO with EDOF presbyopia clinical trial, regulatory compliance, and consumer outreach activities, increased gross margin dollars and flat or slightly decreased gross margin percentages from 2017. These expectations are based on several assumptions, including the following: (i) strong sales growth in China and Korea, (ii) TICL approval in the U.S. by year-end, and (iii) continuing favorable product mix of TICL sales offsetting mid-diopter range ICL lower average selling prices. Also, we will continue our strategic cooperation, practice development and certified training programs.

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

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 29, 2017	December 30, 2016	January 1, 2016
Net sales	100.0%	100.0%	100.0%
Cost of sales	29.1	29.2	31.6
Gross profit	70.9	70.8	68.4
General and administrative	22.8	27.0	25.5
Marketing and selling	31.0	34.5	30.7
Research and development	21.1	24.6	19.1
	74.9	86.1	75.3
Operating loss	(4.0)	(15.3)	(6.9)
Total other income (expense), net	1.5	0.2	(0.4)
Loss before income taxes	(2.5)	(15.1)	(7.3)
Provision (benefit) for income taxes	(0.2)	(0.4)	1.2
Net loss	(2.3)%	(14.7)%	(8.5)%

Net Sales

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

	% of Total	2017	% of Total	2016	% of Total	2015
ICL	75.4%	\$ 68,325	71.7%	\$ 59,111	66.8%	\$ 51,543
IOL	19.0%	17,258	23.9%	19,706	25.8%	19,857
Other	5.6%	5,028	4.4%	3,615	7.4%	5,723
Total Sales	100.0%	\$ 90,611	100.0%	\$ 82,432	100.0%	\$ 77,123

Net sales for 2017 were \$90.6 million, a 9.9% increase over the \$82.4 million reported in fiscal 2016. The increase in net sales was due to increases in ICL sales of \$9.2 million and other product sales of \$1.4 million, partially offset by a \$2.4 million decrease in IOL sales. Changes in foreign currency unfavorably impacted net sales by \$0.5 million.

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.

Total ICL sales for 2017 were \$68.3 million, a 15.6% increase from \$59.1 million reported for fiscal 2016. The sales increase was driven by the APAC region, which grew 23.4% with unit growth of 25.0%, primarily due to increased sales in China, Japan, and APAC distributor markets, partially offset by decreased sales in Korea. The EMEA region, grew 8.4% with unit growth of 7.6%, primarily due to increased sales in Germany, Spain, and EMEA distributor markets, partially offset by decreased sales in Latin America. The North America region grew 1.9% and units grew 1.2%. Changes in foreign currency unfavorably impacted ICL sales by \$0.1 million. ICL sales represented 75.4% of our total sales for fiscal year 2017.

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 18.1% primarily due to a 35.2% increase in China sales and a 50.9% increase in Japan sales, partially offset by a 7.5% decrease in Korea sales, APAC units grew 16.3%; the EMEA region grew by 12.5% primarily due to a 45.7% increase in Germany sales, in part due to the transition to a direct sales model, EMEA unit sales grew 4.2%; and the North American region grew by 7.1% 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 IOL sales were \$17.3 million for fiscal 2017, a decrease of 12.4% from \$19.7 million reported in fiscal 2016. The decline was primarily due to the discontinuance of the silicone IOL product line in the U.S. during 2016 and lower than planned IOL sales in Japan due to production issues with one of the materials used in our silicone IOL preloaded injectors. Changes in foreign currency unfavorably impacted IOL sales by \$0.3 million. IOL sales represented 19.0% of our total sales for fiscal year 2017.

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 5.6%. IOL sales represented 23.9% of our total sales for fiscal year 2016.

Other product sales for the year ended December 29, 2017 were \$5.0 million, a 39.1% increase compared to the \$3.6 million reported for the year ended December 30, 2016. The increase in other product sales is due to an increase in preloaded injector part sales to a third-party manufacturer for product they sell to their customers. Other product sales represented 5.6% of our total sales for fiscal year 2017.

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.

Gross Profit

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

	2017	2016	2015
Gross Profit	\$ 64,280	\$ 58,369	\$ 52,723
Gross Profit Margin	70.9%	70.8%	68.4%

Gross profit for the year ended December 29, 2017 was \$64.3 million, a 10.1% increase compared to the \$58.4 million reported for the year ended December 30, 2016. Gross profit in 2017 increased 10.1%, slightly ahead of the increase in net sales. Gross profit margin increased to 70.9% of revenue for fiscal year 2017 compared to 70.8% of revenue for fiscal year 2016, due to an increase in sales mix of Toric ICLs, improved country mix, lower unit costs and the cost of sales related to the \$0.6 million non-cash charge related to the immediate vesting of all unvested equity awards as a result of the triggering of the "Change of Control" provisions of the Company's equity incentive plan in 2016 which was not repeated in 2017, largely offset by the increased mix of lower margin injector and other product sales and lower ICL and IOL average selling prices.

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, the \$0.6 million non-cash charge related the "Change of Control" provisions as discussed above, and higher other cost of goods sold.

General and Administrative Expense

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

	2017	2016	2015
General and Administrative Expense	\$ 20,665	\$ 22,252	\$ 19,604
Percentage of Sales	22.8%	27.0%	25.5%

General and administrative expenses for the year ended December 29, 2017 were \$20.7 million, a decrease of 7.1% when compared with \$22.3 million reported for the year ended December 30, 2016. The decrease was due to the non-cash charge related to the immediate vesting of all unvested equity awards as a result of the triggering of the "Change of Control" provisions of the Company's equity incentive plan in 2016 which was not repeated in 2017 and decreased salaries, travel and outsourcing expenses in Japan, partially offset by increased headcount and overall compensation, recruiting fees and meeting costs.

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 the \$2.9 million non-cash charge related the "Change of Control" provisions, as discussed above.

Marketing and Selling Expense

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

	<u>2017</u>	<u>2016</u>	<u>2015</u>
Marketing and Selling Expense	\$ 28,130	\$ 28,478	\$ 23,695
Percentage of Sales	31.0%	34.5%	30.7%

Marketing and selling expenses for the year ended December 29, 2017 were \$28.1 million, a decrease of 1.2% when compared with \$28.5 million for the year ended December 30, 2016. The decrease was due to lower stock based compensation expenses due to the non-cash charge related to the immediate vesting of all unvested equity awards as a result of the triggering of the “Change of Control” provisions of the Company’s equity incentive plan in 2016 which was not repeated in 2017, decreased U.S. consulting costs, and decreased salaries, travel and advertising expense in Japan, largely offset by increased commercial operations expenses, travel expense in China and Europe and ESCRS trade show expenses.

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 the \$1.5 million non-cash charge related to the “Change of Control” provisions, as discussed above, advertising, promotional activities, direct selling costs in Germany and trade show expenses, partially offset by decreased U.S. selling expenses.

Research and Development Expense

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

	<u>2017</u>	<u>2016</u>	<u>2015</u>
Research and Development Expense	\$ 19,116	\$ 20,294	\$ 14,761
Percentage of Sales	21.1%	24.6%	19.1%

Research and development expenses for the year ended December 29, 2017 were \$19.1 million, a 5.8% decrease compared to \$20.3 million for the year ended December 30, 2016. The decrease was due to the non-cash charge related to the immediate vesting of all unvested equity awards as a result of the triggering of the “Change of Control” provisions of the Company’s equity incentive plan in 2016 which was not repeated in 2017 and decreased consulting expenses, partially offset by increased headcount, depreciation expense and the write-off of capital equipment no longer in use.

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 (\$1.9 million non-cash charge related to the “Change of Control” provisions, as discussed above)) 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 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):

	<u>2017</u>	<u>2016</u>	<u>2015</u>
Other Income (Expense), net	\$ 1,335	\$ 211	\$ (268)
Percentage of Sales	1.5%	0.2%	(0.4)%

Other income for the year ended December 29, 2017 was \$1.3 million, compared to other income for the year ended December 30, 2016 of \$0.2 million, and \$0.3 million of other expense reported for the year ended January 1, 2016. The increase in 2017 was mainly due to gains on foreign currency transactions compared to losses in 2016. The increase in 2016 is mainly due to decreases of losses on foreign currency transactions compared to 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)	
	2017 v. 2016	2016 v. 2015
Interest expense, net	\$ —	\$ (34)
Foreign exchange	966	802
Royalty income	(37)	(122)
Other	195	(167)
Net change in other income (expense), net	<u>\$ 1,124</u>	<u>\$ 479</u>

Provision (Benefit) for Income Taxes

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

	2017	2016	2015
Provision (Benefit) for Income Taxes	\$ (157)	\$ (315)	\$ 928

The Company recorded a benefit from income taxes for fiscal 2017 due primarily to a U.S. income tax benefit related to an alternative minimum tax carryforward, offset by income tax expense generated from profits in our Swiss and Japan operations.

On December 22, 2017, the United States enacted major tax reform legislation, Public Law No. 115-97, commonly referred to as the 2017 Tax Cuts and Jobs Act (2017 Tax Act), which enacted a broad range of changes to the federal tax code. Under the 2017 Tax Act, corporations are no longer subject to the alternative minimum tax (AMT), effective for taxable years beginning after December 31, 2017. As we have an AMT credit from a prior year, we can carry the credit forward to offset regular tax. To the extent we do not have a federal tax liability, a portion of the credit is now refundable each year starting in 2018, with any remaining balance fully refundable in 2021. As we will ultimately receive a full refund for the credit, the valuation allowance attributable to the AMT credit carryforward was released, creating a deferred tax benefit of \$0.5 million for 2017.

The 2017 Tax Act imposes a repatriation tax on accumulated earnings of foreign subsidiaries, implements a territorial tax system together with a current tax on certain foreign earnings and lowers the general corporate income tax rate to 21.0%. On December 22, 2017, the SEC staff issued Staff Accounting Bulletin No. 118 (SAB 118) that allows us to record provisional amounts during a measurement period not to extend beyond one year of the enactment date. We currently are analyzing the 2017 Tax Act, and in certain areas, have made reasonable estimates of the effects on our Consolidated Financial Statements and tax disclosures, including the amount of the repatriation tax and changes to our existing deferred tax balances. The repatriation tax is based primarily on our accumulated foreign earnings and profits that we previously deferred from U.S. income taxes. As a result, the Company included \$5.7 million in foreign earnings in federal income for the current year. The federal taxable income was fully offset by our net operating loss carryforwards resulting in no federal tax due. In addition, we remeasured certain net deferred tax assets and liabilities based on the tax rates at which they are expected to reverse in the future. The estimated amount recorded related to the remeasurement of these balances was a reduction of our net deferred asset of \$19.1 million, with a corresponding decrease to the valuation allowance. We consider the key estimates on the repatriation tax, net deferred tax remeasurement and the impact on our unrealized tax benefits to be incomplete due to our continuing analysis of final year-end data and tax positions. Our analysis could affect the measurement of these balances and give rise to new deferred tax assets and liabilities. Since the 2017 Tax Act was passed late in the fourth quarter of 2017, and further guidance and accounting interpretation is expected over the next 12 months, our review is still pending. We expect to complete our analysis within the measurement period.

The benefit from income taxes in fiscal 2016, was 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 for fiscal 2015, is primarily due to income tax expense of \$0.9 million 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 2018, 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 flows 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):

	<u>2017</u>	<u>2016</u>	<u>2015</u>	<u>2017 v. 2016</u>	<u>2016 v. 2015</u>
Cash and cash equivalents	\$ 18.5	\$ 14.0	\$ 13.4	\$ 4.5	\$ 0.6
Current assets	\$ 53.9	\$ 49.5	\$ 48.6	\$ 4.4	\$ 0.9
Current liabilities	19.1	21.1	17.5	(2.0)	3.6
Working capital	\$ 34.8	\$ 28.4	\$ 31.1	\$ 6.4	\$ (2.7)

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

Net cash provided by operating activities was \$2.9 million and \$1.0 million for fiscal years 2017 and 2016, respectively, and net cash used in operating activities of \$2.2 million for fiscal year 2015. For 2017, net cash provided by operating activities consisted of \$9.0 million in non-cash items, offset by a \$2.1 million net loss and \$4.0 million in working-capital changes. For 2016, net cash provided by operating activities consisted of \$12.6 million in non-cash items and \$0.5 million in working capital changes, offset by a \$12.1 million net loss. For 2015, net cash used in operating activities consisted of a \$6.5 million net loss and a \$4.2 million in working capital changes, offset by \$8.5 million in non-cash items.

Net cash used in investing activities was \$1.0 million, \$3.2 million and \$2.0 million, for fiscal years 2017, 2016 and 2015 respectively, and relate primarily to the acquisition of property, plant, and equipment. The decrease in investment in property, plant and equipment during 2017, relative to 2016, is primarily due to decreased investments in manufacturing and quality system improvement projects which began in 2016. 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.

Net cash provided by financing activities was \$2.4 million, \$3.0 million and \$4.6 million for fiscal years 2017, 2016 and 2015, respectively. For 2017, net cash provided by financing activities consisted of \$4.0 million in proceeds from the exercise of stock options, offset by \$1.3 million repayment on capital lease obligations and \$0.2 million in the repurchase of common stock shares from employees to satisfy minimum tax withholdings. 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.

Accounts receivable was \$17.9 million as of December 29, 2017 and \$16.3 million as of December 30, 2016. Days’ Sales Outstanding (DSO) was 72 days in 2017 and 2016.

Inventories at the end of fiscal 2017 and 2016 were \$13.3 million and \$14.8 million, respectively. Days’ Inventory on Hand (DOH) was 169 days in 2017 and 216 days in 2016 for finished goods, including consignment inventory. The decrease in DOH is due to increased sales of ICL products.

Shelf Registration

On May 11, 2017, 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 statement became effective on June 9, 2017 and expires on June 9, 2020. 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

We have credit facilities with different lenders to support operations as detailed below.

Line of Credit

Since 1998, our wholly owned Japanese subsidiary, STAAR Japan, has had an agreement 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 0.06% as of December 29, 2017) plus a 0.50% spread, and may be renewed quarterly (the current line expires on February 21, 2018). The credit facility is not collateralized. We had 500,000,000 Yen outstanding on the line of credit as of December 29, 2017 and December 30, 2016 (approximately \$4.4 million and \$4.3 million based on the foreign exchange rates on December 29, 2017 and December 30, 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 29, 2017, there were no available borrowings under the line. At maturity on February 21, 2018, this line of credit was renewed until May 21, 2018, with similar terms.

In September 2013, our wholly owned Swiss subsidiary, STAAR Surgical AG, entered into a framework agreement for loans (“framework agreement”) with Credit Suisse (the “Bank”). The framework agreement provides for borrowings of up to 1,000,000 CHF (Swiss Francs) (approximately \$1.0 million at the rate of exchange on December 29, 2017 and 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 framework agreement is automatically renewed on an annual basis based on the same terms assuming there is no default. The framework agreement may be terminated by either party at any time in accordance with its general terms and conditions. The framework agreement 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 framework 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 29, 2017 and December 30, 2016.

Covenant Compliance

We are in compliance with the covenants of our credit facilities and lines of credit as of December 29, 2017.

Lease Line of Credit (Capital Leases)

On January 31, 2017, we entered into lease schedule 010 with Famam Street Financial, Inc. (“Famam”). 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. We expect to convert this into a \$1.6 million capital lease in the first quarter of 2018.

On January 31, 2017, we entered into lease schedule 009R with Famam. Under 009R, equipment with a cost of \$1,957,000 was 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 we can opt to continue to rent the equipment, return the equipment, or exercise a fair market value purchase option. As of December 29, 2017, approximately \$1.1 million was outstanding on this capital lease.

On June 12, 2014, we entered into lease schedule 008R with Famam. 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 we can opt to continue to rent the equipment, return the equipment, or exercise a fair market value purchase option. The lease schedule was paid off in May 2017 and we returned the equipment in February 2018.

Contractual Obligations

The following table represents the Company's known contractual obligations as of December 29, 2017 (in thousands):

Contractual Obligations	Payments Due by Period				
	Total	1 Year	2-3 Years	4-5 Years	More Than 5 Years
Line of credit (Note 8)*	\$ 4,438	\$ 4,438	\$ –	\$ –	\$ –
Capital lease obligations (Notes 8 and 12)*	1,848	1,309	431	108	–
Operating lease obligations (Note 12)*	6,450	1,956	3,020	1,011	463
Pension benefit payments (Note 10)*	1,797	93	217	299	1,188
Severance (Note 12)*	41	41	–	–	–
Asset retirement obligation (Note 8)*	202	202	–	–	–
Open purchase orders (Note 12)*	3,308	3,308	–	–	–
Total	<u>\$ 18,084</u>	<u>\$ 11,347</u>	<u>\$ 3,668</u>	<u>\$ 1,418</u>	<u>\$ 1,651</u>

* Refer to the Notes to the Consolidated Financial Statements in this Annual Report on Form 10-K.

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 returns, 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 and ICLs 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 lenses have 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 29, 2017.

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 29, 2017.

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

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

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

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

- *Stock-Based Compensation.* We account for the issuance of stock options to employees and directors by estimating the fair value of options issued using the Black-Scholes pricing model. This model’s calculations include the exercise price, the market price of shares on grant date, risk-free interest rates, expected term of the option, expected volatility of our stock and expected dividend yield. The amounts recorded in the financial statements for share-based compensation could vary significantly if we were to use different assumptions. We also issue restricted stock units, or RSUs, which contain a service condition such that they vest if the grantee is still employed with us on a range of measurement dates, which are typically three years after the grant date. On occasion, we also issue RSUs to certain employees which contain a performance condition such that they vest if the internally established target is met or exceeded and the grantee is still employed with us on the measurement date, which is typically one year after the grant date. We recognize compensation cost for the RSUs 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."
- *Goodwill.* Goodwill, which has an indefinite life, is not amortized, but instead is subject to periodic testing for impairment. 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.
- *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 29, 2017, we had \$4.4 million of foreign debt. Our \$4.4 million of foreign debt bears an interest rate that is equal to the uncollateralized overnight call rate in Japan (approximately 0.06%) plus a 0.50% spread. Thus, our interest expense would fluctuate with any change in the base 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 \$44,000.

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 income (expense), 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 29, 2017, 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 29, 2017 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 29, 2017, 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 29, 2017.

Report of Independent Registered Public Accounting Firm

Shareholders and Board of Directors
STAAR Surgical Company
Monrovia, CA

Opinion on Internal Control over Financial Reporting

We have audited STAAR Surgical Company and Subsidiaries' (the "Company's") internal control over financial reporting as of December 29, 2017, based on criteria established in *Internal Control – Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (the "COSO criteria"). In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 29, 2017, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) ("PCAOB"), the consolidated balance sheets of the Company as of December 29, 2017 and December 30, 2016, the related consolidated statements of operations, comprehensive loss, stockholders' equity, and cash flows for each of the three years in the period ended December 29, 2017, and the related notes and schedule and our report dated February 28, 2018 expressed an unqualified opinion thereon.

Basis for Opinion

The 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 are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit of internal control over financial reporting in accordance with the standards of the PCAOB. 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.

Definition and Limitations of Internal Control over Financial Reporting

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.

/s/ BDO USA, LLP

Los Angeles, California
February 28, 2018

Item 9B. Other Information

None.

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 2018 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 29, 2017.

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:

	<u>Page</u>
(1) Consolidated Financial Statements	
Report of Independent Registered Public Accounting Firm	F-2
Consolidated Balance Sheets	F-3
Consolidated Statements of Operations	F-4
Consolidated Statements of Comprehensive Loss	F-5
Consolidated Statements of Stockholders’ Equity	F-6
Consolidated Statements of Cash Flows	F-7
Notes to Consolidated Financial Statements	F-8
(2) Schedules required by Regulation S-X are filed as an exhibit to this report:	
II. Schedule II — Valuation and Qualifying Accounts and Reserves	F-36
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	Amendment No. 1 to Standard Industrial/Commercial Multi-Tenant Lease dated January 3, 2003, by and between the Company and California Rosen LLC.(5)
10.2	Lease Agreement dated July 12, 1994, between STAAR Surgical AG and Calderari and Schwab AG/SA.(6)
10.3	Supplement #1 dated July 10, 1995, to the Lease Agreement of July 12, 1994, between STAAR Surgical AG and Calderari and Schwab AG/SA.(6)
10.4	Supplement #2 dated August 2, 1999, to the Lease Agreement of July 12, 1994, between STAAR Surgical AG and Calderari and Schwab AG/SA.(6)
†10.5	Form of Indemnification Agreement between the Company and certain officers and directors.(6)
†10.6	Employment Agreement, dated December 16, 2004 by and between the Company and Hans Blickensdoerfer. (7)
10.7	Credit Agreement between STAAR Japan Inc. and Mizuho Bank Inc., dated October 31, 2007.(8)
10.8	Amended Credit Agreement between STAAR Japan Inc. and Mizuho Bank Ltd., dated June 30, 2009.(8)
10.9	Amended Credit Agreement between STAAR Japan Inc. and Mizuho Bank Ltd., dated December 28, 2012. (9)
10.10	Basic Agreement on Unsterilized Intraocular Lens Sales Transactions between Canon Staar Co., Inc. and Nidek Co., Ltd., dated May 23, 2005.(10)

10.11	Basic Agreement on Injector Product Sales Transactions between Canon Staar Co., Inc. and Nidek Co., Ltd., dated May 23, 2005.(10)
10.12	Memorandum of Understanding Concerning Basic Agreements for Purchase and Sale between STAAR Japan Inc. and Nidek Co., Ltd., dated December 25, 2008.(10)
10.13	Acrylic Preset Supply Warranty Agreement between STAAR Japan Inc. and Nidek Co., Ltd., dated December 25, 2008.(10)
10.14	Framework Agreement for Loans between Credit Suisse and STAAR Surgical AG, dated September 2013.*
†10.15	Form of Executive Severance Agreement.(11)
†10.16	Form of Executive Change in Control Agreement.(11)
10.17	Standard Industrial/Commercial Single – Tenant Lease – Net dated August 17, 2012, by and between the Company and Pacific Equity Partners, LLC.(12)
†10.18	Letter of the Company dated March 27, 2012 to Samuel Gesten, Vice President and General Counsel, regarding compensation.(9)
†10.19	Letter of the Company dated August 10, 2012 to James Francese, Vice President, Global Marketing, regarding compensation. (9)
†10.20	Letter of the Company dated July 27, 2015 to Keith Holliday, Vice President of Research and Development, regarding compensation. (13)
10.21	Amendment Agreement between STAAR Surgical Company and Nidek Co., Ltd., dated March 31, 2016.(14)
†10.22	Employment Agreement effective March 1, 2015 by and between the Company and Caren Mason, dated March 1, 2015. (15)
10.23	Form of Option Grant and Stock Option Agreement for employees.(16)
10.24	Form of Option Grant and Stock Option Agreement for Non-Employees Directors.(16)
10.25	Form of Restricted Stock Unit Grant and Agreement.(16)
10.26	Form of Restricted Stock Award Grant and Restricted Stock Award Agreement.(16)
10.27	Form of Amendment to Credit Agreement between STAAR Japan Inc. and Mizuho Bank Ltd.*
10.28	Master Lease Agreement dated May 30, 2006 by and between the Company and Farnam Street Financial, Inc.(16)
10.29	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.(16)
10.30	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.(16)
10.31	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.(16)
10.32	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.(16)
10.33	Letter of the Company dated September 27, 2017 to Deborah Andrews, Vice President of Finance, Chief Financial Officer, regarding compensation.(17)
10.34	Lease dated August 10, 2017 by and between the Company and 2000 Gold L.P.(18)
10.35	Lease Agreement dated March 1, 2007, between STAAR Surgical AG and Calderari and Schwab AG/SA.*
14.1	Code of Business Conduct and Ethics.(19)
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 29, 2017 formatted in Extensible Business Reporting Language (XBRL): (i) the Consolidated Balance Sheets, (ii) the Consolidated Statements of Operations, (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.
- ** 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 with the Commission on June 11, 2014.
- (2) Incorporated by reference from the Company’s Quarterly Report on Form 10-Q, for period ended June 30, 2017, as filed with the Commission on August 2, 2017.
- (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 with the Commission on April 18, 2003.
- (4) Incorporated by reference to Appendix 1 of the Company’s Proxy Statement on Form DEF 14A, as filed with the Commission on May 2, 2016.
- (5) Incorporated by reference to the Company’s Annual Report on Form 10-K, for the year ended January 2, 2004, as filed with the Commission on March 17, 2004.

- (6) Incorporated by reference from the Company's Annual Report on Form 10-K, for the year ended December 28, 2004, as filed with the Commission on March 30, 2005.
- (7) Incorporated by reference to the Company's Current Report on Form 8-K as filed with the Commission on October 1, 2009.
- (8) Incorporated by reference to the Company's Quarterly Report on Form 10-Q, for the period ended October 2, 2009, as filed with the Commission on November 12, 2009.
- (9) Incorporated by reference to the Company's Annual Report on Form 10-K, for the year ended December 31, 2012, as filed with the commission on March 12, 2013.
- (10) Incorporated by reference to the Company's Annual Report on Form 10-K, for the year ended January 1, 2010 as filed with the Commission on April 1, 2010.
- (11) Incorporated by reference to the Company's Quarterly Report on Form 10-Q, for the period ended September 30, 2011, as filed with the Commission on November 2, 2011.
- (12) Incorporated by reference to the Company's Current Report on Form 8-K as filed with the Commission on August 23, 2012.
- (13) Incorporated by reference to the Company's Quarterly Report on Form 10-Q, for the period ended October 2, 2015, as filed with the Commission on November 4, 2015.
- (14) Incorporated by reference to the Company's Quarterly Report on Form 10-Q, for the period ended April 1, 2016, as filed with the Commission on May 11, 2016.
- (15) Incorporated by reference to the Company's Current Report on Form 8-K as filed with the Commission on March 3, 2015.
- (16) Incorporated by reference to the Company's Annual Report on Form 10-K, for the year ended December 30, 2016, as filed with the Commission on March 2, 2017.
- (17) Incorporated by reference to the Company's Current Report on Form 8-K as filed with the Commission on September 28, 2017.
- (18) Incorporated by reference to the Company's Quarterly Report on Form 10-Q, for the period ended September 29, 2017, as filed with the Commission on November 8, 2017.
- (19) Incorporated by reference to the Company's Quarterly Report on Form 10-Q/A, for the period ended June 29, 2012, as filed with the Commission on August 8, 2012.

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: February 28, 2018

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.

<u>Name</u>	<u>Title</u>	<u>Date</u>
<u>/s/ Caren Mason</u> Caren Mason	President, Chief Executive Officer and Director (principal executive officer)	February 28, 2018
<u>/s/ Deborah J. Andrews</u> Deborah J. Andrews	Vice President, Chief Financial Officer (principal accounting and financial officer)	February 28, 2018
<u>/s/ Louis E. Silverman</u> Louis E. Silverman	Chairman of the Board, Director	February 28, 2018
<u>/s/ Stephen C. Farrell</u> Stephen C. Farrell	Director	February 28, 2018
<u>/s/ John C. Moore</u> John C. Moore	Director	February 28, 2018
<u>/s/ William P. Wall</u> William P. Wall	Director	February 28, 2018

STAAR SURGICAL COMPANY AND SUBSIDIARIES
CONSOLIDATED FINANCIAL STATEMENTS
Years Ended December 29, 2017, December 30, 2016 and January 1, 2016

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Shareholders and Board of Directors
STAAR Surgical Company
Monrovia, CA

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of STAAR Surgical Company and subsidiaries (the "Company") as of December 29, 2017 and December 30, 2016, the related consolidated statements of operations, comprehensive loss, stockholders' equity, and cash flows for each of the three years in the period ended December 29, 2017, and the related notes and financial statement schedule listed in the accompanying index (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company and subsidiaries at December 29, 2017 and December 30, 2016, and the results of their operations and their cash flows for each of the three years in the period ended December 29, 2017, in conformity with accounting principles generally accepted in the United States of America.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) ("PCAOB"), the Company's internal control over financial reporting as of December 29, 2017, based on criteria established in *Internal Control – Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO") and our report dated February 28, 2018 expressed an unqualified opinion thereon.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ BDO USA, LLP

We have served as the Company's auditor since 1993.

Los Angeles, California
February 28, 2018

STAAR SURGICAL COMPANY AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS
December 29, 2017 and December 30, 2016

	2017	2016
	(In thousands, except par value amounts)	
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 18,520	\$ 13,999
Accounts receivable trade, net	17,853	16,344
Inventories, net	13,310	14,825
Prepayments, deposits, and other current assets	4,207	4,349
Total current assets	<u>53,890</u>	<u>49,517</u>
Property, plant and equipment, net	9,776	11,790
Intangible assets, net	271	473
Goodwill	1,786	1,786
Deferred income taxes	1,242	1,139
Other assets	967	772
Total assets	<u>\$ 67,932</u>	<u>\$ 65,477</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Line of credit	\$ 4,438	\$ 4,283
Accounts payable	6,033	8,311
Obligations under capital leases	1,278	1,198
Other current liabilities	7,339	7,275
Total current liabilities	<u>19,088</u>	<u>21,067</u>
Obligations under capital leases	531	1,339
Deferred income taxes	350	915
Asset retirement obligations	202	195
Deferred rent	172	59
Pension liability	4,653	3,997
Total liabilities	<u>24,996</u>	<u>27,572</u>
Commitments and contingencies (Note 12)		
Stockholders' equity:		
Common stock, \$0.01 par value; 60,000 shares authorized: 41,383 and 40,732 shares issued and outstanding at December 29, 2017 and December 30, 2016, respectively	414	407
Additional paid-in capital	204,920	197,657
Accumulated other comprehensive loss	(1,150)	(1,050)
Accumulated deficit	(161,248)	(159,109)
Total stockholders' equity	<u>42,936</u>	<u>37,905</u>
Total liabilities and stockholders' equity	<u>\$ 67,932</u>	<u>\$ 65,477</u>

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

STAAR SURGICAL COMPANY AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF OPERATIONS

Years Ended December 29, 2017, December 30, 2016 and January 1, 2016

	2017	2016	2015
	(In thousands, except per share amounts)		
Net sales	\$ 90,611	\$ 82,432	\$ 77,123
Cost of sales	26,331	24,063	24,400
Gross profit	<u>64,280</u>	<u>58,369</u>	<u>52,723</u>
Selling, general and administrative expenses:			
General and administrative	20,665	22,252	19,604
Marketing and selling	28,130	28,478	23,695
Research and development	19,116	20,294	14,761
Operating loss	<u>(3,631)</u>	<u>(12,655)</u>	<u>(5,337)</u>
Other income (expense), net:			
Interest expense, net	(112)	(112)	(78)
Gain (loss) on foreign currency transactions	819	(147)	(949)
Royalty income	581	618	740
Other income (expense), net	47	(148)	19
Other income (expense), net	<u>1,335</u>	<u>211</u>	<u>(268)</u>
Loss before provision (benefit) for income taxes	(2,296)	(12,444)	(5,605)
Provision (benefit) for income taxes	(157)	(315)	928
Net loss	<u>\$ (2,139)</u>	<u>\$ (12,129)</u>	<u>\$ (6,533)</u>
Net loss per share – basic and diluted	<u>\$ (0.05)</u>	<u>\$ (0.30)</u>	<u>\$ (0.17)</u>
Weighted average shares outstanding – basic and diluted	<u>41,004</u>	<u>40,329</u>	<u>39,260</u>

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 29, 2017, December 30, 2016 and January 1, 2016

	2017	2016	2015
	(In thousands)		
Net loss	\$ (2,139)	\$ (12,129)	\$ (6,533)
Other comprehensive income (loss):			
Defined benefit plans:			
Net change in plan assets	(483)	317	(673)
Reclassification into selling, general and administrative expenses	71	100	59
Foreign currency translation gain	387	224	52
Tax effect	(75)	(111)	52
Other comprehensive income (loss), net of tax	(100)	530	(510)
Comprehensive loss	<u>\$ (2,239)</u>	<u>\$ (11,599)</u>	<u>\$ (7,043)</u>

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 29, 2017, December 30, 2016 and January 1, 2016
 (In thousands)

	Common Stock Shares	Common Stock Par Value	Additional Paid-In Capital	Accumulated Other Compre-hensive Income (Loss) (AOCI)	Accumulated Deficit	Total
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
Net loss	—	—	—	—	(2,139)	(2,139)
Other comprehensive loss	—	—	—	(100)	—	(100)
Common stock issued upon exercise of options	557	6	3,964	—	—	3,970
Stock-based compensation	—	—	3,533	—	—	3,533
Repurchase of employee common stock for taxes withheld	(24)	—	(234)	—	—	(234)
Unvested restricted stock	21	—	—	—	—	—
Vested restricted stock	97	1	—	—	—	1
Balance, at December 29, 2017	41,383	\$ 414	\$ 204,920	\$ (1,150)	\$ (161,248)	\$ 42,936

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 29, 2017, December 30, 2016 and January 1, 2016

	2017	2016	2015
	(In thousands)		
Cash flows from operating activities:			
Net loss	\$ (2,139)	\$ (12,129)	\$ (6,533)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:			
Depreciation of property, plant, and equipment	3,133	2,664	2,196
Amortization of intangibles	221	228	205
Deferred income taxes	(547)	(1,364)	473
Change in net pension liability	186	491	190
Loss on disposal of property and equipment	623	222	—
Stock-based compensation expense	3,161	8,558	3,304
Provision for sales returns and bad debts	463	205	345
Inventory provision	1,739	1,610	1,799
Changes in working capital:			
Accounts receivable	(1,857)	(771)	(4,952)
Inventories	312	213	(1,472)
Prepayments, deposits, and other current assets	(64)	(851)	856
Accounts payable	(2,501)	1,007	14
Other current liabilities	123	966	1,413
Net cash provided by (used in) operating activities	<u>2,853</u>	<u>1,049</u>	<u>(2,162)</u>
Cash flows from investing activities:			
Acquisition of property and equipment	(1,046)	(3,205)	(2,045)
Sale of property and equipment	—	—	2
Net cash used in investing activities	<u>(1,046)</u>	<u>(3,205)</u>	<u>(2,043)</u>
Cash flows from financing activities:			
Repayment of capital lease obligations	(1,300)	(424)	(391)
Proceeds from sale-leaseback transactions	—	1,546	—
Repurchase of employee common stock for taxes withheld	(234)	(611)	—
Proceeds from the exercise of stock options	3,970	2,438	2,168
Proceeds from vested restricted stock	1	4	2
Proceeds from the exercise of warrants	—	—	2,800
Net cash provided by financing activities	<u>2,437</u>	<u>2,953</u>	<u>4,579</u>
Effect of exchange rate changes on cash, cash equivalents and restricted cash	279	(200)	15
Increase in cash, cash equivalents and restricted cash	<u>4,523</u>	<u>597</u>	<u>389</u>
Cash, cash equivalents and restricted cash, at beginning of year	14,118	13,521	13,132
Cash, cash equivalents and restricted cash, at end of year	<u>\$ 18,641</u>	<u>\$ 14,118</u>	<u>\$ 13,521</u>

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 29, 2017, 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. Certain reclassifications have been made to financial statements of prior years to conform to the current year presentation (see Note 18).

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 2017, 2016 and 2015 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 2017, 2016 and 2015, the net foreign translation gains were \$387,000, \$224,000 and \$52,000, respectively, and net foreign currency transaction gain (loss), included in the Consolidated Statements of Operations were \$819,000, (\$147,000) and (\$949,000), 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 29, 2017, 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 and ICLs 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 lenses have been implanted.

STAAR SURGICAL COMPANY AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 1 — Organization and Description of Business and Accounting Policies (Continued)

Revenue Recognition (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 29, 2017 and 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 29, 2017 and 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)

Note 1 — Organization and Description of Business and Accounting Policies (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 reserves, 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 29, 2017, there was one customer who accounted for 24% of the Company's consolidated trade receivables. As of December 30, 2016, there were two customers who accounted for 22% and 11% of the Company's 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 26% of the Company's consolidated net sales in fiscal 2017, one customer who accounted for 19% of the Company's consolidated net sales in fiscal 2016 and two customers who accounted for 15% and 10% of the Company's consolidated net sales in fiscal 2015.

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 net realizable value. 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.

STAAR SURGICAL COMPANY AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 1 — Organization and Description of Business and Accounting Policies (Continued)

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.

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 29, 2017 and December 30, 2016, the carrying value of goodwill was \$1,786,000.

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 29, 2017 and December 30, 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 \$6,102,000, \$6,160,000 and \$3,917,000, for fiscal 2017, 2016 and 2015, respectively.

STAAR SURGICAL COMPANY AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 1 — Organization and Description of Business and Accounting Policies (Continued)

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.

On December 22, 2017, the SEC staff issued Staff Accounting Bulletin No. 118 ("SAB 118") to address the accounting implications of the Public Law No. 115-97, or commonly referred to as the 2017 Tax Cuts and Jobs Act ("2017 Tax Act"). The effects of the 2017 Tax Act are recognized upon enactment, however, SAB 118 permits a company to recognize provisional amounts when it does not have the necessary information available, prepared or analyzed (including computations) in reasonable detail to complete its accounting for the change in tax law. The measurement period to finalize the Company's calculations cannot extend beyond one year of the enactment date. Key provisions that have a significant impact on the Company's Consolidated Financial Statements and where the Company has recognized estimated amounts include the recognition of liabilities for taxes on repatriation of accumulated foreign earnings and the remeasurement of certain net deferred and other tax liabilities.

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).

STAAR SURGICAL COMPANY AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 1 — Organization and Description of Business and Accounting Policies (Continued)

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 executive officers and employees, and one year for members of its Board of Directors (the “Board”) (see Note 11).

The Company also, at times, issues restricted stock to its executive officers, employees and 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 executive officers 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 Balance Sheets and the Consolidated Statements of Comprehensive Loss. Total comprehensive income (loss) includes, in addition to the net 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 29, 2017, December 30, 2016 and January 1, 2016 (in thousands):

	Foreign Currency Translation	Defined Benefit Pension Plan- Japan	Defined Benefit Pension Plan- Switzerland	Accumulated Other Comprehensive Income (Loss)
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)	426	641
Tax effect	(68)	2	(45)	(111)
Balance at December 30, 2016	11	88	(1,149)	(1,050)
Other comprehensive income (loss)	387	(6)	(406)	(25)
Tax effect	(120)	6	39	(75)
Balance at December 29, 2017	<u>\$ 278</u>	<u>\$ 88</u>	<u>\$ (1,516)</u>	<u>\$ (1,150)</u>

STAAR SURGICAL COMPANY AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 1 — Organization and Description of Business and Accounting Policies (Continued)

Recently Adopted Accounting Pronouncements

During the year ended December 29, 2017, the Company adopted Financial Accounting Standards Board (“FASB”) Accounting Standards Update (“ASU”) 2015-11, “Simplifying 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 Company adopted this standard as of December 31, 2016 (beginning of FY 2017). The adoption of ASU 2015-11 did not have a material effect on the Consolidated Financial Statements.

During the year ended December 29, 2017, the Company adopted ASU 2015-17, “Income Taxes (Topic 740): Balance Sheet Classification of Deferred Taxes”, on a retrospective basis, which changes how deferred taxes are classified on the Company’s balance sheets. Accordingly, the Company adjusted the December 30, 2016 balance sheet for current and noncurrent deferred tax assets to conform to the presentation for the current year due to the adoption of ASU 2015-17. The ASU eliminates the requirement to present deferred tax liabilities and assets as current and noncurrent on the balance sheet. Instead, companies are required to classify all deferred tax assets and liabilities as noncurrent. The Company adopted this standard as of December 31, 2016 (beginning of FY 2017). The adoption of ASU 2015-17 did not have a material effect on the Consolidated Financial Statements.

During the year ended December 29, 2017, the Company adopted ASU 2016-09, “Compensation—Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting”, which simplified 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 Company adopted this standard as of December 31, 2016 (beginning of FY 2017). The adoption of ASU 2016-09 did not have a material effect on the Consolidated Financial Statements and prior periods were not restated.

During the year ended December 29, 2017, the Company adopted ASU 2016-18, “Statement of Cash Flows (Topic 230): Restricted Cash”, that requires that the statement of cash flows explain the change during the period in the total of cash, cash equivalents, and restricted cash and that restricted cash be included with cash and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts shown on the Consolidated Statements of Cash Flows. The Company early adopted this standard as of December 31, 2016 (beginning of FY 2017). The adoption of ASU 2016-18 did not have a material effect on the Consolidated Financial Statements, however, prior period restricted cash was added to beginning and ending cash and cash equivalents in the Consolidated Statements of Cash Flows to conform to the current presentation.

The following table provides a reconciliation of cash, cash equivalents, and restricted cash reported within the Consolidated Balance Sheets that sum to the total of the same such amounts shown in the Consolidated Statements of Cash Flows (in 000’s):

	<u>2017</u>	<u>2016</u>	<u>2015</u>	<u>2014</u>
Cash and cash equivalents	\$ 18,520	\$ 13,999	\$ 13,402	\$ 13,013
Restricted cash included in other long-term assets	121	119	119	119
Total cash, cash equivalents and restricted cash as shown in the Consolidated Statements of Cash Flows	<u>\$ 18,641</u>	<u>\$ 14,118</u>	<u>\$ 13,521</u>	<u>\$ 13,132</u>

The Company has restricted cash of approximately \$121,000 set aside as collateral for a standby letter of credit required by the California Department of Public Health for unforeseen future regulatory costs related to the decommissioning of certain manufacturing equipment.

During the year ended December 29, 2017, the Company adopted ASU 2017-04, “Intangibles—Goodwill and Other (Topic 350)”, 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 early adopted this standard as of December 31, 2016 (beginning of FY2017). The adoption of ASU 2017-04 did not have a material effect on the Consolidated Financial Statements.

On December 22, 2017, the United States enacted major tax reform legislation, the 2017 Tax Act, which enacted a broad range of changes to the federal tax code. The 2017 Tax Act, among other things, includes lowering the U.S. federal tax rates (21 percent flat tax rate), imposes additional limitations on the deductibility of interest and net operating losses, allows for the expensing of capital expenditures, and puts into effect a number of changes impacting operations outside of the United States including, but not limited to, the imposition of a one-time tax “deemed repatriation” on accumulated offshore earnings not previously subject to tax, and shifts the U.S. taxation of multinational corporations from a worldwide system of taxation to a territorial system. SAB 118 allows corporations to record provisional amounts during a measurement period not to extend beyond one year of the enactment date. The Company is currently analyzing the 2017 Tax Act, and in certain areas, have made reasonable estimates of the effects on its Consolidated Financial Statements and tax disclosures, including the amount of the repatriation tax and changes to its existing deferred tax balances.

STAAR SURGICAL COMPANY AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 1 — Organization and Description of Business and Accounting Policies (Continued)

Recent Accounting Pronouncements Not Yet Adopted

In May 2017, the FASB issued ASU 2017-09, “Compensation – Stock Compensation (Topic 718): Scope of Modification Accounting,” which amends the scope of modification accounting for share-based payment arrangements, provides guidance on the types of changes to the terms or conditions of share-based payment awards to which an entity would be required to apply modification accounting under ASC 718. For all entities, the ASU is effective for annual reporting periods, including interim periods within those annual reporting periods, beginning after December 15, 2017. Early adoption is permitted, including adoption in any interim period. The Company will adopt this standard as of December 30, 2017 (beginning of FY 2018) and does not expect the adoption of the standard will have a material impact on its Consolidated Financial Statements.

In March 2017, the FASB issued ASU 2017-07, “Compensation-Retirement Benefits (Topic 715): Improving the Presentation of Net Periodic Pension Cost and Net Periodic Postretirement Benefit Cost.” The standard requires that an employer report the service cost component in the same line items as other compensation costs arising from services rendered by the pertinent employees during the period. The other components of net benefit cost are required to be presented in the income statement separately from the service cost component and outside of operating profit. The standard is effective for public companies for annual periods beginning after December 15, 2017, including interim periods within those annual periods. Prior periods are required to be recast. The Company will adopt this standard as of December 30, 2017 (beginning of FY 2018) and does not expect the adoption of the standard will have a material impact on its Consolidated Financial Statements.

In October 2016, the FASB issued ASU 2016-16, “Income Taxes (Topic 740): Intra-Entity Transfers of Assets Other Than Inventory”, which removes the prohibition in ASC 740 against the immediate recognition of the current and deferred income tax effects of intra-entity transfers of assets other than inventory. The ASU is effective for public companies for fiscal years beginning after December 15, 2017, and interim periods within those annual periods. The ASU should be applied on a modified retrospective basis, recognizing the effects in retained earnings as of the beginning of the year of adoption. The Company will adopt this standard as of December 30, 2017 (beginning of FY 2018) and does not expect the adoption of the standard will have a material impact 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 (beginning of FY 2018) and the Company does not expect the adoption of the standard will have a material impact 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 gathering data to evaluate the impact the adoption of ASU 2016-02 may have on its Consolidated Financial Statements and expects to complete the evaluation by the third quarter of 2018.

STAAR SURGICAL COMPANY AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 1 — Organization and Description of Business and Accounting Policies (Continued)

Recent Accounting Pronouncements Not Yet Adopted (Continued)

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 August 2015, ASU 2014-09 was amended by ASU No. 2015-14, “Revenue from Contracts with Customers (Topic 606): Deferral of the Effective Date”, which defers the effective date of ASU 2014-09 by one year for all entities and permits early adoption on a limited basis. ASU 2014-09 was subsequently amended by four additional pronouncements: (i) ASU No. 2016-10, “Revenue from Contracts with Customers (Topic 606): Identifying Performance Obligations and Licensing;” (ii) ASU No. 2016-11, “Revenue Recognition (Topic 605) and Derivatives and Hedging (Topic 815): Rescission of SEC Guidance Because of Accounting Standards Updates 2014-09 and 2014-16 Pursuant to Staff Announcements at the March 3, 2016 EITF Meeting;” (iii) ASU No. 2016-12, “Revenue from Contracts with Customers (Topic 606): Narrow-Scope Improvements and Practical Expedients;” and (iv) ASU No. 2016-20, “Revenue from Contracts with Customers (Topic 606): Technical Corrections and Improvements to Topic 606”.

The Company completed its assessment and of the new standard, including a detailed review of its revenue streams and contracts. The majority of the Company’s revenue relates to the sale of implantable lenses (ICLs and IOLs) for which revenue is recognized at a point in time (i.e., typically at shipping point, except for certain customers and for our STAAR Japan subsidiary, which is typically recognized when the customer receives the product), which is the point that control transfers to the customer. The Company has determined that the adoption of the new standard will not materially impact the revenue recognition for these transactions. The Company has also determined that it will make accounting policy elections to 1) treat shipping and handling activities that occur after the customer obtains control of the goods as fulfillment costs, and 2) exclude sales and other similar taxes from the measurement of the transaction price. The Company has determined that the adoption of the new standard will not have a material impact on its Consolidated Financial Statements. The Company is still evaluating the effect the standard will have on its financial statement disclosures. The Company expects to apply the modified retrospective method to adopt the standard on December 30, 2017 (beginning of FY 2018) and has determined that there will be no cumulative effect adjustment on its Consolidated Financial Statements.

Note 2 — Accounts Receivable Trade, Net

Accounts receivable trade, net consisted of the following at December 29, 2017 and December 30, 2016 (in thousands):

	<u>2017</u>	<u>2016</u>
Domestic	\$ 804	\$ 1,018
Foreign	19,580	17,382
	<u>20,384</u>	<u>18,400</u>
Less allowance for doubtful accounts and sales returns	2,531	2,056
Total	<u>\$ 17,853</u>	<u>\$ 16,344</u>

Note 3 — Inventories, Net

Inventories, net consisted of the following at December 29, 2017 and December 30, 2016 (in thousands):

	<u>2017</u>	<u>2016</u>
Raw materials and purchased parts	\$ 2,506	\$ 2,264
Work in process	1,996	1,924
Finished goods	11,169	14,268
	<u>15,671</u>	<u>18,456</u>
Less inventory reserves	2,361	3,631
Total	<u>\$ 13,310</u>	<u>\$ 14,825</u>

STAAR SURGICAL COMPANY AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 4 — Prepayments, Deposits, and Other Current Assets

Prepayments, deposits, and other current assets consisted of the following at December 29, 2017 and December 30, 2016 (in thousands):

	<u>2017</u>	<u>2016</u>
Prepayments and deposits	\$ 1,435	\$ 1,003
Prepaid insurance	943	935
Income tax receivable	181	686
Consumption tax receivable	541	573
Value added tax (VAT) receivable	910	668
Other current assets*	197	484
Total	<u>\$ 4,207</u>	<u>\$ 4,349</u>

* No individual item in "other current assets" exceeds 5% of the total prepayments, deposits and other current assets.

Note 5 — Property, Plant and Equipment, Net

Property, plant and equipment, net consisted of the following at December 29, 2017 and December 30, 2016 (in thousands):

	<u>2017</u>	<u>2016</u>
Machinery and equipment	\$ 16,562	\$ 19,807
Furniture and fixtures	9,201	8,025
Leasehold improvements	9,631	9,179
	35,394	37,011
Less accumulated depreciation	25,618	25,221
Total	<u>\$ 9,776</u>	<u>\$ 11,790</u>

Depreciation expense for the years ended December 29, 2017, December 30, 2016 and January 1, 2016, was approximately \$3,133,000, 2,664,000 and \$2,196,000, respectively. The Company recognized losses on disposal of property, plant and equipment of \$623,000, and \$222,000 for the years ended December 29, 2017 and December 30, 2016, respectively. The loss recognized for the year ended December 29, 2017 consisted primarily of an asset, with a net book value of \$599,000, that was no longer in use.

Note 6 — Intangible Assets, Net

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

	<u>December 29, 2017</u>			<u>December 30, 2016</u>		
	<u>Gross Carrying Amount</u>	<u>Accumulated Amortization</u>	<u>Net</u>	<u>Gross Carrying Amount</u>	<u>Accumulated Amortization</u>	<u>Net</u>
Amortized intangible assets:						
Patents and licenses	\$ 9,244	\$ (8,973)	\$ 271	\$ 9,224	\$ (8,930)	\$ 294
Customer relationships	1,392	(1,392)	—	1,343	(1,209)	134
Developed technology	885	(885)	—	854	(809)	45
Total	<u>\$ 11,521</u>	<u>\$ (11,250)</u>	<u>\$ 271</u>	<u>\$ 11,421</u>	<u>\$ (10,948)</u>	<u>\$ 473</u>

Aggregate amortization expense for intangible assets was \$221,000, \$228,000 and \$205,000, for the years ended December 29, 2017, December 30, 2016 and January 1, 2016, respectively.

STAAR SURGICAL COMPANY AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 6 — Intangible Assets, Net (Continued)

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

Fiscal Year	Amount
2018	\$ 33
2019	33
2020	33
2021	33
2022	33
Thereafter	106
Total	<u>\$ 271</u>

Note 7 — Other Current Liabilities

Other current liabilities consisted of the following at December 29, 2017 and December 30, 2016 (in thousands):

	2017	2016
Accrued salaries and wages	\$ 2,375	\$ 2,334
Accrued insurance	565	501
Accrued consumption tax	446	424
Accrued income taxes	210	1,095
Accrued bonuses	2,058	1,414
Other*	1,685	1,507
Total	<u>\$ 7,339</u>	<u>\$ 7,275</u>

* No individual item in "Other" exceeds 5% of the other current liabilities.

Note 8 — Liabilities

Lines of Credit

Since 1998, the Company's wholly owned Japanese subsidiary, STAAR Japan, has had an agreement 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 0.06% as of December 29, 2017) plus a 0.50% spread, and may be renewed quarterly (the current line expires on February 21, 2018). The credit facility is not collateralized. The Company had 500,000,000 Yen outstanding on the line of credit as of December 29, 2017 and December 30, 2016 (approximately \$4,438,000 and \$4,283,000 based on the foreign exchange rates on December 29, 2017 and December 30, 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 29, 2017, there were no available borrowings under the line. At maturity on February 21, 2018, this line of credit was renewed until May 21, 2018, with similar terms.

In September 2013, the Company's wholly owned Swiss subsidiary, STAAR Surgical AG, entered into a framework agreement for loans ("framework agreement") with Credit Suisse (the "Bank"). The framework agreement provides for borrowings of up to 1,000,000 CHF (Swiss Francs) (approximately \$1,000,000 at the rate of exchange on December 29, 2017 and 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 framework agreement is automatically renewed on an annual basis based on the same terms assuming there is no default. The framework agreement may be terminated by either party at any time in accordance with its general terms and conditions. The framework agreement 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 framework 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 29, 2017 and December 30, 2016.

STAAR SURGICAL COMPANY AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 8 — Liabilities (Continued)

Lease Line of Credit (Capital Leases) (Continued)

On January 31, 2017, the Company entered into lease schedule 010 with Farnam Street Financial, Inc. (“Farnam”). The line of credit provides for borrowings of up to \$2,000,000 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. The Company expects to convert this into a \$1,600,000 capital lease in the first quarter of 2018.

On January 31, 2017, the Company entered into lease schedule 009R with Farnam. Under 009R, equipment with a cost of \$1,957,000 was 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. As of December 29, 2017, approximately \$1,067,000 was outstanding on this capital lease.

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. The lease schedule was paid off in May 2017 and the Company returned the equipment in February 2018.

Covenant Compliance

The Company is in compliance with covenants of its credit facilities and lines of credit as of December 29, 2017.

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 \$202,000 and \$195,000, representing the fair value of the ARO liability obligation in noncurrent liabilities at December 29, 2017 and December 30, 2016, respectively. The lease expires in 2018, however, the Company has no plans to vacate the facility and will start negotiations during 2018 to extend the lease beyond 2018.

Note 9 — Income Taxes

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

	<u>2017</u>	<u>2016</u>	<u>2015</u>
Current tax provision:			
U.S. federal	\$ —	\$ —	\$ —
State	12	18	12
Foreign	378	1,031	443
Total current provision	<u>390</u>	<u>1,049</u>	<u>455</u>
Deferred tax provision (benefit):			
U.S. federal and state	(546)	—	—
Foreign provision	(1)	(1,364)	473
Total deferred provision (benefit)	<u>(547)</u>	<u>(1,364)</u>	<u>473</u>
Provision (benefit) for income taxes	<u>\$ (157)</u>	<u>\$ (315)</u>	<u>\$ 928</u>

As of December 29, 2017, the Company had federal net operating loss carryforwards of \$132,506,000 available to reduce future income taxes of its U.S. operations. The federal net operating loss carryforwards expire in varying amounts between 2020 and 2037. In California, the main state from which the Company conducts its domestic operations, the Company has state net operating losses of \$23,807,000 available to reduce future California income taxes. The California net operating loss carryforwards expire in varying amounts between 2028 and 2037.

The Company had accrued net income taxes payable of \$29,000 and \$409,000 at December 29, 2017 and December 30, 2016, respectively, primarily due to taxes owed in foreign jurisdictions.

STAAR SURGICAL COMPANY AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 9 — Income Taxes (Continued)

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):

	2017		2016		2015	
Computed provision (benefit) for taxes based on income at statutory rate	34.0%	\$ (781)	34.0%	\$ (4,231)	34.0%	\$ (1,905)
Increase (decrease) in taxes resulting from:						
Permanent differences	(0.9)	21	(3.0)	373	(0.6)	33
Change in the future federal tax rate	(832.9)	19,125	—	—	—	—
State minimum taxes, net of federal income tax benefit	(0.4)	8	(0.1)	12	(0.1)	8
State tax benefit	8.3	(190)	6.2	(767)	(6.6)	370
Tax rate difference due to foreign statutory rate	(1.2)	29	(8.9)	1,109	1.6	(90)
Expiration of state net operating tax loss carryforwards	(36.5)	836	(7.2)	892	(47.3)	2,650
Foreign earnings not permanently reinvested, net of the participation exemption	108.1	(2,482)	6.5	(809)	(9.8)	547
Foreign dividend withholding	(0.3)	7	3.8	(478)	(3.8)	211
Expiration of charitable contribution carryover	—	—	(0.1)	12	(0.3)	15
Other	(2.6)	59	1.2	(151)	2.5	(140)
Valuation allowance	731.2	(16,789)	(29.9)	3,723	13.8	(771)
Effective tax provision (benefit) rate	6.8%	<u>\$ (157)</u>	2.5%	<u>\$ (315)</u>	(16.6)%	<u>\$ 928</u>

The Company recorded an income tax benefit of \$157,000 during the fiscal year 2017 due primarily to a U.S. income tax benefit related to an alternative minimum tax carryforward (see discussion below – U.S. Federal Income Tax Reform), offset by income tax expense generated from profits in its foreign operations. 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.

Included in the state tax provision is a decrease to the state deferred tax asset and corresponding decrease to the valuation allowance of \$646,000, \$125,000 and \$3,020,000, for 2017, 2016 and 2015 respectively, primarily related to the expiration of state net operating loss carryforwards.

Included in the foreign deferred tax benefit is a decrease in foreign deferred liabilities of \$47,000 and \$617,000 for 2017 and 2016, respectively. For 2015, there was an increase in foreign deferred liabilities of \$172,000.

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 and 2015 there were no withholding taxes paid to foreign jurisdictions and there were no earnings repatriated from foreign subsidiaries. For 2017, based on the newly enacted 2017 Tax Act, the Company was deemed to repatriate and include in its federal taxable income, \$5,658,000 of unremitted (not previously taxed) earnings from its foreign subsidiaries (see discussion below – U.S. Federal Income Tax Reform). The Company anticipates using net operating loss carryforwards to offset the tax liability from the deemed repatriation.

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. For 2017, the federal portion of the deferred tax assets and liabilities were revalued from 34 percent to 21 percent (see discussion below – U.S. Federal Income Tax Reform). Significant components of the Company's deferred tax assets (liabilities) as of December 29, 2017 and December 30, 2016 are as follows (in thousands):

STAAR SURGICAL COMPANY AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 9 — Income Taxes (Continued)

	<u>2017</u>	<u>2016</u>
Deferred tax assets:		
Allowance for doubtful accounts and sales returns	\$ 230	\$ 244
Inventories	381	662
Accrued vacation	322	437
Accrued other expenses	559	596
Stock-based compensation	1,444	2,154
Pensions	720	625
Depreciation and amortization	959	1,060
Net operating loss carryforwards	33,770	53,232
Business, foreign, AMT and R&D credit carryforwards	3,706	1,665
Prepaid Expenses	188	—
Capitalized R&D	941	920
Other	92	94
Valuation allowance	(40,656)	(57,446)
Total deferred tax assets	<u>\$ 2,656</u>	<u>\$ 4,243</u>
Deferred tax liabilities:		
Foreign tax withholding	\$ (881)	\$ (881)
Amortization of R&D	(723)	(670)
Net Foreign earnings not permanently reinvested	(160)	(2,468)
Total deferred tax liabilities	<u>(1,764)</u>	<u>(4,019)</u>
Total net non-current deferred tax assets	<u>\$ 892</u>	<u>\$ 224</u>

As of December 29, 2017, the Company had net deferred tax liabilities in Switzerland of \$377,000 (which included \$881,000 of withholding taxes on unremitted foreign earnings) and net deferred tax assets of \$722,000 in Japan included in the Company's components of deferred income tax assets and liabilities table. 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.

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 29, 2017, with the exception of the \$546,000 alternative minimum tax credit (see discussion below – U.S. Federal Income Tax Reform). 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.

STAAR SURGICAL COMPANY AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 9 — Income Taxes (Continued)

Foreign Jurisdictions

STAAR Surgical AG

Due to STAAR Surgical AG's history of profits, the deferred tax assets are considered fully realizable. The Company had net deferred tax assets in Switzerland of \$505,000 and \$407,000 as of December 29, 2017 and December 30, 2016, respectively.

STAAR Japan, Inc.

Since 2012, STAAR Japan functions as a limited-risk distributor with a guaranteed return from STAAR AG and accordingly, STAAR Japan's deferred tax assets are considered fully realizable. The Company had net deferred tax assets of \$722,000 and \$698,000 as of December 29, 2017 and December 30, 2016, respectively.

U.S. Federal Income Tax Reform

As discussed in Note 1, on December 22, 2017, the United States enacted major tax reform legislation, the 2017 Tax Act, which enacted a broad range of changes to the federal tax code. On December 22, 2017, the SEC staff issued SAB 118 that allows corporations to record provisional amounts during a measurement period not to extend beyond one year of the enactment date. The Company is currently analyzing the 2017 Tax Act, and in certain areas, has made reasonable estimates of the effects on their Consolidated Financial Statements and tax disclosures, including the amount of the repatriation tax and changes to its existing deferred tax balances.

Most of the changes from the new law are effective for years beginning after December 31, 2017, with the noted exception of the deemed repatriation of the offshore earnings. As a result, the Company included \$5,658,000 in foreign earnings in federal income for the current year. The federal taxable income was offset by the Company's net operating loss carryforwards resulting in no federal tax due. In addition, the Company remeasured certain net deferred tax assets and liabilities based on the tax rates at which they are expected to reverse in the future. The estimated amount recorded related to the remeasurement of these balances was a reduction to the Company's net deferred asset of \$19,125,000, with a corresponding decrease to the valuation allowance. The Company considers the key estimates on the repatriation tax and net deferred tax remeasurement to be incomplete due to its continuing analysis of final year-end data and tax positions. The Company's analysis could affect the measurement of these balances and give rise to new deferred and other tax assets and liabilities. Since the 2017 Tax Act was passed late in the fourth quarter of 2017, and further guidance and accounting interpretation is expected over the next 12 months, the Company review is still pending. The Company expects to complete its analysis within the measurement period.

Also under the 2017 Tax Act, corporations are no longer subject to the alternative minimum tax ("AMT"), effective for taxable years beginning after December 31, 2017. As the Company has an AMT credit from a prior year, the Company can carry the credit forward to offset regular tax. To the extent the Company does not have a federal tax liability, a portion of the credit is now refundable each year starting in 2018, with any remaining balance fully refundable in 2021. As the Company will ultimately receive a full refund for the credit, the valuation allowance attributable to the AMT credit carryforward was released, creating a deferred tax benefit of \$546,000 for 2017.

Other Income Tax Disclosures

The following tax years remain subject to examination:

Significant Jurisdictions	Open Years
U.S. Federal	2014 – 2016
California	2013 – 2016
Switzerland	2016
Japan	2015 – 2016

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

	2017	2016	2015
Domestic	\$ (3,318)	\$ (10,399)	\$ (7,678)
Foreign	1,022	(2,045)	2,073
	<u>\$ (2,296)</u>	<u>\$ (12,444)</u>	<u>\$ (5,605)</u>

STAAR SURGICAL COMPANY AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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 29, 2017 and December 30, 2016 (in thousands):

	<u>2017</u>	<u>2016</u>
Change in Projected Benefit Obligation:		
Projected benefit obligation, beginning of period	\$ 6,363	\$ 6,349
Service cost	381	469
Interest cost	53	65
Participant contributions	260	230
Benefits deposited (paid)	(185)	(340)
Actuarial loss (gain)	721	(410)
Prior service credit	(148)	—
Projected benefit obligation, end of period	<u>\$ 7,445</u>	<u>\$ 6,363</u>
Change in Plan Assets:		
Plan assets at fair value, beginning of period	\$ 3,606	\$ 3,498
Actual return on plan assets (including foreign currency impact)	203	(12)
Employer contributions	260	230
Participant contributions	260	230
Benefits deposited (paid)	(185)	(340)
Plan assets at fair value, end of period	<u>\$ 4,144</u>	<u>\$ 3,606</u>
Funded status pension liability, end of year	<u>\$ (3,301)</u>	<u>\$ (2,757)</u>
Amount Recognized in Accumulated Other Comprehensive Loss, net of tax:		
Actuarial loss on plan assets	\$ (932)	\$ (816)
Actuarial loss on benefit obligation	(1,902)	(1,393)
Actuarial gain recognized in current year	527	454
Prior service credit	184	(6)
Effect of curtailments	609	606
Accumulated other comprehensive loss	<u>\$ (1,514)</u>	<u>\$ (1,155)</u>
Accumulated benefit obligation at end of year	<u>\$ (6,932)</u>	<u>\$ (5,980)</u>

The underfunded balance of \$3,301,000 and \$2,757,000 was included in other long-term liabilities (pension liability) on the consolidated balance sheets as of December 29, 2017 and December 30, 2016, respectively.

STAAR SURGICAL COMPANY AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 10 — Employee Benefit Plans (Continued)

Defined Benefit Plan-Switzerland (Continued)

Net periodic pension cost associated with the Swiss Plan during the years ended December 29, 2017, December 30, 2016 and January 1, 2016 include the following components (in thousands):

	<u>2017</u>	<u>2016</u>	<u>2015</u>
Service cost	\$ 381	\$ 469	\$ 316
Interest cost	53	65	74
Expected return on plan assets	(94)	(89)	(93)
Actuarial loss recognized in current year	72	111	64
Prior service credit	(7)	(7)	—
Net periodic pension cost	<u>\$ 405</u>	<u>\$ 549</u>	<u>\$ 361</u>

Changes in other comprehensive income (loss), net of tax, associated with the Swiss Plan in the year ended December 29, 2017, December 30, 2016 and January 1, 2016 include the following components (in thousands):

	<u>2017</u>	<u>2016</u>	<u>2015</u>
Current year actuarial gain (loss) on plan assets	\$ 97	\$ (8)	\$ 61
Current year actuarial loss on benefit obligation	(645)	(269)	(699)
Actuarial gain (loss) recorded in current year	65	(98)	57
Prior service credit	126	(6)	64
Effect of curtailments	3	—	—
Change in other comprehensive loss	<u>\$ (354)</u>	<u>\$ (381)</u>	<u>\$ (517)</u>

The amount in accumulated other comprehensive loss as of December 29, 2017 that is expected to be recognized as a component of the net periodic pension costs during fiscal year 2018 is \$114,000.

Net periodic pension cost and projected and accumulated pension obligation for the Company's Swiss Plan were calculated on December 29, 2017 and December 30, 2016 using the following assumptions:

	<u>2017</u>	<u>2016</u>
Discount rate	0.7%	0.8%
Salary increases	2.0%	2.0%
Expected return on plan assets	2.5%	2.5%
Expected average remaining working lives in years	10.2	10.0

The discount rates are based on an assumed duration of the pension obligations and estimated using the rates of returns for AAA and AA-rated Swiss and foreign CHF-denominated corporate bonds listed on the SIX Swiss Exchange.

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

STAAR SURGICAL COMPANY AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 10 — Employee Benefit Plans (Continued)

Defined Benefit Plan-Switzerland (Continued)

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).

The table below sets forth the fair value of Plan assets at December 30, 2016 and December 29, 2017, and the related activity in fiscal years 2016 and 2017, in accordance with ASC 715-20-50-1(d) (in thousands):

	Insurance Contracts (Level 3)
Beginning balance at January 1, 2016	\$ 3,498
Actual return on plan assets	(12)
Purchases, sales, and settlement	120
Ending balance at December 30, 2016	3,606
Actual return on plan assets	203
Purchases, sales, and settlement	335
Ending balance at December 29, 2017	<u>\$ 4,144</u>

During fiscal 2018, the Company expects to make cash contributions totaling approximately \$282,000 to the Swiss Plan.

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

Fiscal Year	Amount
2018	\$ 48
2019	53
2020	58
2021	64
2022	71
Thereafter	458
Total	<u>\$ 752</u>

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 SURGICAL COMPANY AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 10 — Employee Benefit Plans (Continued)

Defined Benefit Plan-Japan (Continued)

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 29, 2017 and December 30, 2016 is as follows (in thousands):

	2017	2016
Change in Projected Benefit Obligation:		
Projected benefit obligation, beginning of period	\$ 1,240	\$ 1,035
Service cost	147	148
Interest cost	4	6
Actuarial gain	32	49
Benefits paid	(116)	(17)
Foreign exchange adjustment	45	19
Projected benefit obligation, end of period	<u>\$ 1,352</u>	<u>\$ 1,240</u>
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	<u>\$ —</u>	<u>\$ —</u>
Funded status (pension liability), end of period	<u>\$ (1,352)</u>	<u>\$ (1,240)</u>
Amount Recognized in Accumulated Other Comprehensive Income, Net of Tax:		
Transition obligation	\$ (7)	\$ (14)
Actuarial gain (loss)	(35)	(31)
Prior service cost	8	8
Net gain (loss)	122	125
Accumulated other comprehensive income	<u>\$ 88</u>	<u>\$ 88</u>
Accumulated benefit obligation at end of year	<u>\$ (1,158)</u>	<u>\$ (1,078)</u>

The underfunded balance of \$1,352,000 and \$1,240,000, respectively, was included in other long-term liabilities (pension liability) on the consolidated balance sheets as of December 29, 2017 and December 30, 2016.

Net periodic pension cost associated with the Japan Plan for the years ended December 29, 2017, December 30, 2016 and January 1, 2016 includes the following components (in thousands):

	2017	2016	2015
Service cost	\$ 147	\$ 148	\$ 121
Interest cost	4	6	6
Net amortization of transition obligation	11	12	11
Actuarial loss	(1)	(13)	(15)
Prior service credit	(3)	(1)	(2)
Net periodic pension cost	<u>\$ 158</u>	<u>\$ 152</u>	<u>\$ 121</u>

Changes in other comprehensive income (loss), net of tax, associated with the Japan Plan for the years ended December 29, 2017, December 30, 2016 and January 1, 2016 include the following components (in thousands):

STAAR SURGICAL COMPANY AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 10 — Employee Benefit Plans (Continued)

Defined Benefit Plan-Japan (Continued)

	2017	2016	2015
Amortization of net transition obligation	\$ 7	\$ 8	\$ 7
Amortization of actuarial gain (loss)	(1)	25	(21)
Actuarial income (loss) recorded in current year	(19)	(40)	(10)
Change in other comprehensive income (loss)	<u>\$ (13)</u>	<u>\$ (7)</u>	<u>\$ (24)</u>

The amount in accumulated other comprehensive loss as of December 29, 2017 that is expected to be recognized as a component of the net periodic pension cost in fiscal 2018 is approximately \$9,000.

Net periodic pension cost and projected and accumulated pension obligation for the Company's Japan Plan were calculated on December 29, 2017 and December 30, 2016 using the following assumptions:

	2017	2016
Discount rate	0.3%	0.3%
Salary increases	6.2%	6.0%
Expected return on plan assets	N/A	N/A
Expected average remaining working lives in years	9.08	8.84

The discount rates are based on the yield curve of corporate bonds rated AA or higher. 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
2018	\$ 46
2019	51
2020	56
2021	101
2022	62
Thereafter	729
Total	<u>\$ 1,045</u>

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 29, 2017, 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 29, 2017, December 30, 2016 and January 1, 2016, the Company made contributions, net of forfeitures, of \$764,000, \$703,000 and \$625,000, respectively, to the 401(k) Plan.

STAAR SURGICAL COMPANY AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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 \$6,857,000 non-cash charge to stock-based compensation in the Consolidated Statements of Operations on that date (\$4,569,000 for stock options and \$2,280,000 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: \$2,931,000 in general and administrative expenses, \$1,527,000 in marketing and selling expenses, \$1,838,000 in research and development expenses and \$561,000 in manufacturing costs. Approximately \$3,338,000 of the \$6,857,000 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 29, 2017:

	Fair Value
Stock Options	\$ 4,985
Restricted Stock Units	3,586
Restricted Stock	200
Total	\$ 8,771

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

	Fiscal Year Ended		
	December 29, 2017	December 30, 2016	January 1, 2016
Employee stock options	\$ 1,731	\$ 5,485	\$ 2,306
Restricted stock	186	298	485
Restricted stock units	1,226	2,717	452
Consultant compensation	18	58	61
Total	\$ 3,161	\$ 8,558	\$ 3,304

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

	Fiscal Year Ended		
	December 29, 2017	December 30, 2016	January 1, 2016
Cost of Sales	\$ 8	\$ 612	\$ 52
General and administrative	1,487	3,809	2,090
Marketing and selling	805	1,961	696
Research and development	861	2,176	466
Total stock-based compensation expense	3,161	8,558	3,304
Amounts capitalized as part of inventory	372	269	516
Total stock-based compensation	\$ 3,533	\$ 8,827	\$ 3,820

STAAR SURGICAL COMPANY AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 11 — Stockholders' Equity (Continued)

As of December 29, 2017, there was \$8,151,000 of total unrecognized compensation cost related to non-vested share-based compensation arrangements granted under the Plan (\$4,616,000 for stock options and \$3,535,000 for restricted stock and restricted stock units). That cost was expected to be recognized over a weighted-average period of approximately two years.

Incentive Plan

The Amended and Restated 2003 Omnibus Equity Incentive Plan ("the Plan") provides for various forms of stock-based incentives. To date, of the available forms of awards under the Plan, the Company has granted only stock options, restricted stock, unrestricted share grants, and restricted stock units ("RSUs"). Options under the plan are granted at fair market value on the date of grant, become exercisable generally over a three-year period, or as determined by the Board of Directors, and expire over periods not exceeding 10 years from the date of grant. Certain option and share awards provide for accelerated vesting if there is a change in control and pre-established financial metrics are met (as defined in the Plan). Grants of restricted stock outstanding under the Plan generally vest over periods of one to three years. Grants of RSUs outstanding under the Plan generally vest based on service, performance, or a combination of both. On June 24, 2016, stockholders approved a proposal to increase the number of shares under the Plan by 1,900,000 shares, for a total of 13,150,000 shares. As of December 29, 2017, there were 1,098,758 shares available for grant under the Plan.

Assumptions

The fair value of each option award is estimated on the date of grant using a Black-Scholes option valuation model applying the weighted-average assumptions noted in the following table. Expected volatilities are based on historical volatility of the Company's stock. The expected term of options granted is derived from the historical exercises and post-vesting cancellations, and represents the period of time that options granted are expected to be outstanding. The Company has calculated an 11% estimated forfeiture rate based on historical forfeiture experience. The risk-free rate is based on the U.S. Treasury yield curve corresponding to the expected term at the time of the grant.

	Fiscal Year Ended		
	December 29, 2017	December 30, 2016	January 1, 2016
Expected dividend yield	0%	0%	0%
Expected volatility	57%	57%	57%
Risk-free interest rate	1.96%	1.34%	1.59%
Expected term (in years)	5.67	5.57	5.57

A summary of option activity under the Plan for the year ended December 29, 2017 is presented below:

Options	Shares (000's)	Weighted- Average Exercise Price	Weighted- Average Remaining Contractual Term (years)	Aggregate Intrinsic Value (000's)
Outstanding at December 30, 2016	3,502	\$ 8.28		
Granted	956	10.19		
Exercised	(557)	7.12		
Forfeited or expired	(176)	11.62		
Outstanding at December 29, 2017	<u>3,725</u>	\$ 8.78	6.96	\$ 25,069
Exercisable at December 29, 2017	<u>2,577</u>	\$ 8.38	6.00	\$ 18,395

STAAR SURGICAL COMPANY AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 11 — Stockholders' Equity (Continued)

A summary of unvested options activity under the Plan for the year ended December 29, 2017 is presented below:

Options	Shares (000's)	Weighted- Average Grant-Date Fair Value
Unvested at December 30, 2016	662	\$ 3.84
Granted during the year	956	5.42
Forfeited or expired during the year	(176)	5.53
Vested during the year	(294)	5.14
Unvested at December 29, 2017	<u>1,148</u>	<u>\$ 4.96</u>

The weighted-average grant-date fair value of options granted during the fiscal years ended December 29, 2017, December 30, 2016 and January 1, 2016 were \$5.42, \$3.77, and \$4.14 per option respectively. The total intrinsic value of options exercised during the fiscal years ended December 29, 2017, December 30, 2016 and January 1, 2016, were \$3,065,000, \$1,737,000 and \$2,048,000, respectively.

Restricted stock

A summary of restricted stock activity for the year ended December 29, 2017 is presented below:

Restricted Stock	Shares (000's)	Weighted Average Grant-Date Fair Value per Share
Outstanding at December 30, 2016	23	\$ 6.47
Granted	21	9.60
Vested	(23)	6.47
Outstanding at December 29, 2017	<u>21</u>	<u>\$ 9.60</u>

Restricted Stock Units

A summary of restricted stock units' activity for the year ended December 29, 2017 is presented below:

	Units (000's)	Weighted Average Grant-Date Fair Value per Share
Outstanding at December 30, 2016	274	\$ 7.60
Granted	345	10.39
Vested	(96)	7.76
Forfeited or expired	(35)	8.81
Outstanding at December 29, 2017	<u>488</u>	<u>\$ 9.45</u>

STAAR SURGICAL COMPANY AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 12 — Commitments and Contingencies

Lease Obligations

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

Estimated future minimum lease payments under leases having initial or remaining non-cancelable lease terms more than one year as of December 29, 2017 are as follows (in thousands):

Fiscal Year	Operating Leases	Capital Leases
2018	\$ 1,956	\$ 1,309
2019	1,611	307
2020	1,409	124
2021	548	104
2022	463	4
Thereafter	463	—
Total minimum lease payments	\$ 6,450	\$ 1,848
Less amounts representing interest	—	39
	<u>\$ 6,450</u>	<u>\$ 1,809</u>

Rent expense was approximately \$2,436,000, \$2,243,000 and \$1,198,000, for the years ended December 29, 2017, December 30, 2016 and January 1, 2016, respectively.

The Company had the following assets under capital lease at December 29, 2017 and December 30, 2016 (in thousands):

	2017	2016
Machinery and equipment	\$ 4,311	\$ 5,650
Furniture and fixtures	2,285	704
Leasehold improvements	155	124
	6,751	6,478
Less accumulated depreciation	4,239	3,359
	<u>\$ 2,512</u>	<u>\$ 3,119</u>

Depreciation expense for assets under capital lease for each of the years ended December 29, 2017, December 30, 2016 and January 1, 2016, was approximately \$388,000, \$195,000 and \$176,000, respectively.

As of December 29, 2017, there were open purchase orders of \$3,308,000 and severance payable of \$41,000.

Indemnification Agreements

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

STAAR SURGICAL COMPANY AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 12 — Commitments and Contingencies (Continued)

Tax Filings

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

Employment Agreements

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

Litigation and Claims

From time to time the Company may be subject to various claims and legal proceedings arising out of the normal course of our business. These claims and legal proceedings may relate to contractual rights and obligations, employment matters, and claims of product liability. The most significant of these actions, proceedings and investigations are described below. STAAR maintains insurance coverage for product liability and certain securities claims. Legal proceedings can extend for several years, and most of the matters concerning the Company are at early stages of the legal and administrative process. As a result, these matters have not yet progressed sufficiently through discovery and/or development of important factual information and legal issues to enable the Company to determine whether the proceedings are material to the Company or to estimate a range of possible loss, if any. Unless otherwise disclosed, the Company is unable to estimate the possible loss or range of loss for the legal proceedings described below. While it is not possible to accurately predict or determine outcomes of these items, an adverse determination in one or more of these items currently pending could have a material adverse effect on the Company's Consolidated Statements of Operations, Balance Sheets, or Statements of Cash Flows.

Stockholder Securities Litigation: Todd Action

On July 8, 2014, a putative securities class action lawsuit was filed by Edward Todd against STAAR and three officers in the U.S. District Court for the Central District of California. The plaintiff claims that STAAR made misleading statements to and omitted material information from our investors between February 27, 2013 and September 29, 2014 about alleged regulatory violations at STAAR's Monrovia manufacturing facility. On October 20, 2014, plaintiff amended its complaint, dismissed two Company officers, added one other officer, reduced the alleged Class Period to November 1, 2013 through September 29, 2014, and demanded compensatory damages and attorneys' fees. On January 5, 2017, the court granted plaintiff's Motion for Class Certification. On June 20, 2017, plaintiff sought preliminary approval of a proposed class action settlement in the amount of \$7,000,000. The settlement documents filed by the plaintiff included a "Stipulation and Agreement of Settlement" that provided, among other things, that the \$7,000,000 settlement amount "shall be wired on behalf of all Defendants and Released Persons out of insurance proceeds from STAAR's Insurance Policies into the Settlement Escrow Account." The Company determined it was probable the insurance carriers would satisfy their obligation. On July 10, 2017, the court granted the plaintiff's application for preliminary approval of the class action settlement. On or about July 28, 2017, the Company's insurance carriers directly funded the entire settlement amount to the court-authorized escrow account. On October 23, 2017, the court granted plaintiff's application for final approval of the class action settlement in the amount of \$7,000,000. A third-party claims administrator will administer and oversee the distribution of the settlement funds to qualified class members, pursuant to the process approved by the court.

STAAR SURGICAL COMPANY AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 12 — Commitments and Contingencies (Continued)

Litigation and Claims (Continued)

Stockholder Derivative Litigation: Forestal Action

On June 21, 2016, Kevin Forestal filed a stockholder derivative complaint against our then-current Board of Directors, which included Caren Mason, Mark B. Logan, Stephen C. Farrell, Richard A. Meier, John C. Moore, J. Steven Roush, Louis E. Silverman, and William P. Wall, and STAAR as well as Barry G. Caldwell and John S. Santos in the U.S. District Court for the Central District of California. The plaintiff alleges breaches of fiduciary duties by, among other things, allowing STAAR to disseminate misleading statements to investors regarding the condition of the Company's Quality System, failing to properly oversee the Company, and unjust enrichment. The complaint seeks damages, restitution and governance reforms, attorneys' fees, and costs. On January 31, 2017, the court granted the Company's Motion to Dismiss. On February 6, 2017, plaintiff filed a Notice of Appeal and on July 17, 2017 plaintiff filed his appellate brief. On September 14, 2017, the Company filed its appellate answering brief. Although the ultimate outcome of this action cannot be determined with certainty, the Company believes that the allegations in the Complaint are without merit. The Company has not recorded any loss or accrual in the accompanying Consolidated Financial Statements at December 29, 2017 for this matter as the likelihood and amount of loss, if any, has not been determined and is not currently estimable.

Note 13 — Related Party Transactions

The Company has made various advances to certain non-executive employees. Amounts due from employees included in prepayments, deposits, and other current assets at December 29, 2017 and December 30, 2016 were \$12,000 and \$37,000, respectively.

Note 14 — Supplemental Disclosure of Cash Flow Information

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

	2017	2016	2015
Non-cash operating activities:			
Insurance receivable	\$ 7,000	\$ —	\$ —
Settlement liability	\$ 7,000	\$ —	\$ —
Non-cash investing and financing activities:			
Assets obtained by capital lease	\$ 563	\$ 2,383	\$ 91
Purchase of property and equipment included in accounts payable	\$ 121	\$ 485	\$ 51
Cash paid:			
Interest	\$ 90	\$ 112	\$ 121
Taxes	\$ 881	\$ 699	\$ 589

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

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

	2017	2016	2015
Numerator:			
Net loss	\$ (2,139)	\$ (12,129)	\$ (6,533)
Denominator:			
Weighted average common shares and denominator for basic calculation:			
Weighted average common shares outstanding	41,025	40,352	39,384
Less: Unvested restricted stock	(21)	(23)	(124)
Denominator for basic calculation	41,004	40,329	39,260
Weighted average effects of potentially dilutive common stock:	—	—	—
Denominator for diluted calculation	41,004	40,329	39,260
Net loss per share – basic and diluted	\$ (0.05)	\$ (0.30)	\$ (0.17)

STAAR SURGICAL COMPANY AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

Because the Company had a net loss for the years ended December 29, 2017, December 30, 2016 and January 1, 2016, the number of diluted shares is equal to the number of basic shares. Outstanding options and warrants to purchase common stock, restricted stock and restricted stock units would have had an anti-dilutive effect on diluted per share amounts. The following table sets forth (in thousands) the weighted average number of options and warrants to purchase shares of common stock, restricted stock, and restricted stock units with either exercise prices or unrecognized compensation cost per share greater than the average market price per share of the Company's common stock, which were not included in the calculation of diluted per share amounts because the effects would be anti-dilutive.

	<u>2017</u>	<u>2016</u>	<u>2015</u>
Options	2,237	4,069	2,506
Warrants	—	—	345
Restricted stock and restricted stock units	203	76	190
Total	<u>2,440</u>	<u>4,145</u>	<u>3,041</u>

Note 16 — Geographic and Product Data

The Company markets and sells its products in more than 75 countries and conducts its manufacturing in the United States. Other than the Japan, China, the United States, and Korea, the Company does not conduct business in any country in which its sales in that country exceed 10% of consolidated net sales. Sales are attributed to countries based on location of customers. The composition of the Company's sales to unaffiliated customers is set forth below (in thousands):

Net sales to unaffiliated customers	<u>2017</u>	<u>2016</u>	<u>2015</u>
Japan	\$ 17,424	\$ 17,329	\$ 16,982
China	23,881	16,019	12,571
United States	7,894	9,859	10,904
Korea	5,543	7,455	8,061
Others*	35,869	31,770	28,605
Total	<u>\$ 90,611</u>	<u>\$ 82,432</u>	<u>\$ 77,123</u>

*No other location individually exceeds 10% of total sales.

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

Net sales by product line	<u>2017</u>	<u>2016</u>	<u>2015</u>
ICLs	\$ 68,325	\$ 59,111	\$ 51,543
IOLs	17,258	19,706	19,857
Other surgical products	5,028	3,615	5,723
Total	<u>\$ 90,611</u>	<u>\$ 82,432</u>	<u>\$ 77,123</u>

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

Long-lived assets	<u>2017</u>	<u>2016</u>
U.S.	\$ 8,523	\$ 10,704
Switzerland	912	737
Japan	612	822
Total	<u>\$ 10,047</u>	<u>\$ 12,263</u>

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

STAAR SURGICAL COMPANY AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 17 — Quarterly Financial Data (Unaudited)

Summary unaudited quarterly financial data from continuing operations for fiscal 2017 and 2016 is as follows (in thousands except per share data). The Company has derived this data from the unaudited consolidated interim financial statements that, in the Company's opinion, have been prepared on substantially the same basis as the audited financial statements contained elsewhere in this report and include all normal recurring adjustments necessary for a fair presentation of the financial information for the periods presented. These unaudited quarterly results should be read in conjunction with the financial statements and notes thereto included elsewhere in this report. The operating results in any quarter are not necessarily indicative of the results that may be expected for any future period.

December 29, 2017	1st Qtr.	2nd Qtr.	3rd Qtr.	4th Qtr.
Net sales	\$ 20,350	\$ 21,936	\$ 23,473	\$ 24,852
Gross profit	14,577	15,474	16,849	17,380
Net (loss) income	(2,203)	(971)	1,173	(138)
Net (loss) income per share – basic and diluted	(0.05)	(0.02)	0.03	(0.00)

December 30, 2016	1st Qtr.	2nd Qtr.	3rd Qtr.	4th Qtr.
Net sales	\$ 19,269	\$ 20,974	\$ 20,052	\$ 22,137
Gross profit	12,993	14,626	14,872	15,878
Net loss	(8,041)	(2,143)	(1,778)	(167)
Net loss per share – basic and diluted	(0.20)	(0.05)	(0.04)	(0.00)

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

Note 18 — Reclassifications

In accordance with the adoption of ASU 2015-17, the Company reclassified current deferred tax and long-term deferred income tax liability to long-term deferred tax asset on the Consolidated Balance Sheet for the year ended 2016 and updated classifications of items within deferred tax assets and deferred tax liabilities in Note 9.

The Company made several reclassifications in the disclosure in the Consolidated Statements of Comprehensive Loss for the years ended 2016 and 2015. The Company separately stated the tax effect and expanded adjustments in pension liability into the reclassification related to the change in plan assets and the reclassification related to selling, general and administrative expenses.

The Company reclassified inventory reserves from Changes in Working Capital – Inventory in the Statements of Cash Flows to the non-cash section of the Statements of Cash Flows for the years ended 2016 and 2015.

STAAR SURGICAL COMPANY AND SUBSIDIARIES

SCHEDULE II — VALUATION AND QUALIFYING ACCOUNTS AND RESERVES

Column A	Column B	Column C	Column D	Column E
Description	Balance at Beginning of Year	Additions	Deductions	Balance at End of Year
(In thousands)				
2017				
Allowance for doubtful accounts and sales returns deducted from accounts receivable in the balance sheet	\$ 2,056	\$ 483	\$ 8	\$ 2,531
Deferred tax asset valuation allowance	57,446	2,253	19,043	40,656
	<u>\$ 59,502</u>	<u>\$ 2,736</u>	<u>\$ 19,051</u>	<u>\$ 43,187</u>
2016				
Allowance for doubtful accounts and sales returns deducted from accounts receivable in the balance sheet	\$ 1,877	\$ 206	\$ 27	\$ 2,056
Deferred tax asset valuation allowance	53,333	4,513	400	57,446
	<u>\$ 55,210</u>	<u>\$ 4,719</u>	<u>\$ 427</u>	<u>\$ 59,502</u>
2015				
Allowance for doubtful accounts and sales returns deducted from accounts receivable in the balance sheet	\$ 1,589	\$ 345	\$ 57	\$ 1,877
Deferred tax asset valuation allowance	54,104	2,249	3,020	53,333
	<u>\$ 55,693</u>	<u>\$ 2,594</u>	<u>\$ 3,077</u>	<u>\$ 55,210</u>

OTC Transactions

Prior to concluding an "OTC Transaction" the Bank may request that a legally binding master agreement for over-the-counter (OTC) derivatives acceptable to the Bank is agreed between the Borrower and the Bank.

There is, however, no obligation on the part of the Bank to enter into any "OTC Transactions" (cf. OTC Master Agreement).

The OTC Master Agreement also applies to any other "OTC Transactions", which are concluded independently of and outside the scope of this framework agreement between the Bank and the Borrower.

Interest Rate

- Current account overdrafts

The interest rate is determined by the Bank. The interest rate is based, among other things, on the prevailing conditions on the money and capital markets.

The Bank may at any time and with immediate effect adjust the interest rate to reflect changes in conditions on the money and capital markets and/or changes in the Bank's risk assessment without sending a separate notification.

The current interest rates are printed on the account statements.

- Fixed advances

Interest rates may be agreed upon without any requirements as of form; an oral agreement, in particular, is sufficient for the interest rate to be binding. The interest rate is based, among other things, on prevailing conditions on the money and capital markets (taking account of the term and currency).

- General

If the currently valid capital requirements are increased through measures by authorities or provisions of law, the Bank reserves the right to pass on the resulting additional borrowing costs on to the Borrower by increasing the interest rate.

Interest Due Date

Interest falls due in each case upon the account closing (cf. "Account Closings" below).

The interest may be debited to an account of the Borrower.

Commissions

Upon utilization of the loan in the form of a current account overdraft, a credit commission is payable by the Borrower as of the end of each quarter, in the amount of 0.25% per quarter on the average outstanding loan amount.

If the current account overdraft limit is exceeded, a commission of 1% per quarter on the average amount of the limit excess is payable by the Borrower as of the end of the quarter. Overdrafts may be exceeded only in exceptional only after prior consultation with the Bank and only in exceptional cases.

The Borrower must pay the commissions determined by the Bank on contingent liabilities of the Bank (e.g. guarantees, documentary credits and bills of exchange).

Fees

The Bank may charge fees for reviewing, changing, monitoring and managing the credit facility and the individual loans as well as for extraordinary expenses. The Bank reserves the right to introduce and amend fees at any time.

The Bank will inform the Borrower of its fees and any amendments thereof in an appropriate manner. The applicable fees may be viewed at the Bank.

Account Closings

Current accounts are closed four times per year as of the end of each quarter.

Statements are provided on maturity for fixed advances with a term of up to 12 months.

Risks

The Bank expressly informs the Borrower that taking up loans by using securities and/or cash account balances as collateral and/or the utilization of the loan proceeds (leveraging) for investments in financial instruments of any kind (securities, derivatives, OTC / TOFF, FX etc.) also involves an interest rate, price and currency risk.

The Borrower is made aware of the following risks in particular: In case of adverse market developments, the assets pledged as collateral may be insufficient to cover the outstanding credit in full, so that at a time that is unfavorable for the Borrower the collateral may have to be realized and the open positions may have to be closed out respectively liquidated. To the extent the realization of the available collateral is insufficient to cover the Bank's claim from the loan, the Borrower remains based on the credit relationship personally liable vis-à-vis the Bank for the full discharge of the remaining debt.

Borrower's Affirmative Obligations

• **Obligation to Provide Information**

The Borrower is obliged to inform the Bank without delay of current business developments and significant changes in its management and in its direct and/or indirect participation/control relationships as well as other significant changes that could influence the Borrower's financial situation.

In particular, the Borrower is obliged to submit the following documents to the Bank:

- Annually:
the balance sheet, profit and loss account and notes to the financial statements, together with the complete auditor's report and budget and, if available, the commercial (internal) account statements, within four months after the closing date

Late Payment

The Borrower will be in default with immediate effect, without any reminder by the Bank, if he/she/it fails to fulfill a payment obligation under this framework agreement and/or any agreements based on the framework agreement when it falls due.

Ordinary termination

- Framework agreement
This framework agreement may be terminated by either party at any time with immediate effect.

Upon termination of the framework agreement, all limits and other utilization options under this framework agreement lapse; in particular, any current account overdraft that has been granted will fall due for repayment immediately or on a repayment date determined by the Bank. Where legally permissible, the Bank may, at its discretion, give early notice on or terminate any of its contingent liabilities.

Irrespective of termination of the framework agreement, fixed advances shall continue to run until maturity; the following provisions on early termination and an automatic acceleration of the due date remain reserved. Following termination of the framework agreement, fixed advances may not be extended nor may any new fixed advances be claimed.

- Credit limits
A credit limit, in particular a current account overdraft, may be terminated or reduced by either party at any time with immediate effect.
- General
The termination or maturity of a loan granted under this framework agreement does not automatically result in the termination of this framework agreement.

Maturity of a Fixed Advance

Subject to an extension or early termination, every fixed advance automatically falls due for repayment upon maturity, without any need for a notice of termination.

The Bank is entitled to debit a fixed advance that is due for repayment to an account of the Borrower.

Early Termination

The Bank is entitled at any time and with immediate effect to declare all fixed advances (fixed term) and loans with an agreed notice period granted under this framework agreement, plus all accrued interest, commission and fees, to be immediately due and payable upon the occurrence of one of the following events:

- General
 - the Borrower is more than 30 calendar days in arrears on an interest payment or repayment of the principal;

- the Borrower has breached another obligation under this framework agreement and/or any agreements based hereon and has failed or was unable to restore the proper contractual situation within 30 calendar days following receipt of written notice from the Bank;
 - bankruptcy proceedings have been instituted against the Borrower or a third party provider of collateral, one of them has been granted a debt restructuring moratorium or deferral of bankruptcy, or one of them has concluded a debt restructuring agreement in or out of court;
 - in the Bank's view, the Borrower's asset and/or revenue situation has deteriorated significantly.
- For companies
 - in the Bank's view, has been a material change in the Borrower's direct or indirect participation/control relationships;
 - the Borrower has entered into a merger or demerger agreement either as the acquired company or the acquiring company or transferred significant assets to a third party (including within the Borrower's group of companies);
 - the auditor's report contains a material qualification.

Settlement of Costs in the Event of Early Termination of Fixed Advances

If any fixed advances granted under this framework agreement are terminated early, the Bank will credit or debit the Borrower with the interest gain or interest shortfall accrued thereon. This is calculated based on the difference between the contractual interest rate which applies at the time of termination and the interest rate that, in the Bank's view, can be earned on an investment with the same residual term on the money or capital markets at the time of termination, multiplied by the outstanding loan amount and the residual term. Any surplus in favor of the Borrower is set off against the fee for the Bank's expenses described below.

In addition a flat fee of 0.1% of the loan amount, but not less than CHF 1'000.00, is owed for the Bank's expenses.

Release from Contingent Liabilities/ Cash Cover

If this framework agreement and/or a credit line with regard to contingent liabilities of the Bank (e.g. guarantee limit) is terminated, the Bank is entitled to request the Borrower to release it from its current contingent liabilities (e.g. by discharge) within 10 calendar days of the termination.

If the Bank cannot or can only be partially released from the liability within the above deadline or if a release of the Bank in full is shown to be impossible from the outset, the Borrower is obliged to pay the total countervalue of the outstanding contingent liabilities in the relevant currency and amount to the accounts designated by the Bank (including accounts opened for this purpose) at the Bank's first demand, to the preclusion of any protests or objections. Upon payment into these accounts, the corresponding account credit shall be deemed to have been pledged to the Bank by the Borrower as collateral against any recourse based on the existing contingent liabilities.

Credit Risk Hedging

In order for the Bank to directly or indirectly insure or hedge credit risk arising from this credit relationship or collateral underlying the credit, the Bank may, at any time, disclose data and information associated with the credit relationship and the credit risk evaluation required for buying credit protection or credit insurance from a third party. Such hedging and insurance transactions do not entail a transfer of all or any part of this credit relationship or its servicing to a third party.

Data and information may be disclosed to third parties in Switzerland or abroad, namely to hedging or insurance providers, such as banks, financial institutions, credit insurers, hedge funds or to other entities offering credit protection. In the context of such hedging transactions data and information may also be disclosed to other parties involved within the scope of such hedging or insurance transactions, such as rating agencies.

These third parties shall be obliged to keep such transferred data and information confidential and to handle it securely which is subject to the local legal and regulatory provisions governing secrecy and data protection obligations.

Restrictions

The Borrower undertakes not to use the funds under this framework agreement for business activities relating to Iran, Myanmar (Burma), North Korea, Sudan, Cuba, and Syria or for business activities relating to other countries that are subject to economic and trade sanctions as communicated by the Bank to the Borrower. Furthermore, the Borrower undertakes not to use the funds under this framework agreement for business activities that are subject to sanctions/embargos imposed by the Swiss State Secretariat for Economic Affairs (SECO), the United Nations (UN), the European Union (EU) and/or the US Office of Foreign Assets Control (OFAC). This includes in particular business activities involving persons named on any sanctions lists issued by one of the above-mentioned bodies.

Additional Agreements and Special Contractual Terms

The additional agreements that must be concluded or have already been concluded in accordance with the terms of this framework agreement and the agreed loan products (including the special contractual terms applicable to the individual loan products) form an integral part of this framework agreement.

Should any provisions of this framework agreement contradict those of the additional agreements and/or any special contractual terms, then these provisions/contractual terms shall take precedence over the provisions of this framework agreement.

General Conditions

The Bank's "General Conditions including the Safe Custody Regulations" supplement this framework agreement.

Place of Performance

The place of performance is the location of the Swiss branch of the Bank with which the Borrowers have a contractual relationship. For Borrowers whose present or future domicile is outside Switzerland, the place of performance shall also be the place of debt enforcement ("special domicile" as defined in Art. 50 par. 2 of the Federal Law on Debt Collection and Bankruptcy).

Applicable law and place of jurisdiction

This framework agreement and the agreements based on this framework agreement are subject to and shall be construed in accordance with Swiss law.

The Borrower recognizes the exclusive jurisdiction of the courts of **Zurich** or of the location of the branch of the Bank with which the contractual relationship exists. The Bank also has the right to bring legal action against the Borrower before any other competent court.

Issuance/Signing of Agreement

This framework agreement is being issued and signed in duplicate. The Borrower and the Bank shall each receive one specimen hereof.

This framework agreement replaces the loan agreement of August 23, 2010, but shall not effect any novation of the Borrower's existing debts as defined in Art. 116 of the Swiss Code of Obligations.

CREDIT SUISSE AG

/s/ Pascal De Maddalena
Pascal De Maddalena

/s/ Beat Henzi
Beat Henzi

Biel, 20 September 2013

Staar Surgical AG

/s/ Regina DeWilde /s/ Philippe Subrin
Borrower's signature

Nidau, 14, November 2013
Place and date

"General Conditions including Safe Custody Regulations"

Loan Application (Market Fund-use)

Mizuho Bank Ltd.

Address	1-5-2, Irifune, Urayasu-shi, Chiba Prefecture
	Postal code 279-0012
Name	STAAR Japan LLC

I am applying for the following transaction under the following terms and conditions.
 Note that this document does not automatically constitute a financing agreement or pledge to finance.

To Wit

Details of the transaction (Indicated with the relevant)

Transaction Type	Loan on bill <input type="radio"/> Special overdraft <input type="checkbox"/>				
Requested Transaction Amt (Start amount with ¥)	Billion ¥	Million 5 0 0	Thousand 0 0 0	Yen 0 0 0	
Scheduled Transaction Date					
Scheduled Repayment Date					
Repayment Method	<input checked="" type="checkbox"/> Lump sum payment on expiry <input type="checkbox"/> First installment payment: MMDDYY in the amount of: _____ yen. Subsequently: Every __ months on __ day in the amount of _____ yen. However, the final payment is in the amount of: _____ yen.				
Interest Rate	<input type="checkbox"/> Annually _____ % <input type="checkbox"/> _____ (_____ months) + annual _____ % (initial interest rate: Annually %)				
Interest Payment Method	<input checked="" type="checkbox"/> Prepaid on scheduled transaction date <input type="checkbox"/> Deferred until scheduled repayment date <input type="checkbox"/> Prepaid on scheduled transaction date and __ day every __ months as of ____ MMDDYY <input type="checkbox"/> Deferred payment on __ day every __ months as of ____ MMDDYY <input type="checkbox"/> _____				
Revision of Applicable Interest rate	<input checked="" type="checkbox"/> Apply same interest rate until scheduled repayment date <input type="checkbox"/> Revise each interest payment date <input type="checkbox"/> Revise every __ months as of ____ MMDDYY				
Interest Calculation Method	<input checked="" type="checkbox"/> 365 pro-rated - <input type="checkbox"/> 360 pro-rated / <input type="checkbox"/> Include start and end dates - <input type="checkbox"/> Include one of start or end date				
If Repayment Date Is Holiday	<input checked="" type="checkbox"/> Prior business day <input type="checkbox"/> Following business day				
Other Terms & Conditions					

End

(Bank-use Only)

If concluded by telephone after receiving submission of agreement when final decision on interest rate - Time of call: Hour __ minutes __ date __ - Call to/from: Client - Mr./Ms. _____ Bank - Mr. Ms. _____ - Details of the call: _____ _____

CMR	Approval No.	Loan No.
Supervisor	Verifier	Manager

Special Overdraft Refund Request (Overdraft-use only)

November 21, 2017		Please start amount with ¥.			
Name 1-5-2, Irifune, Urayasu-shi, Chiba Prefecture Postal code 279-0012 STAAR Japan LLC Representative: STAAR Surgical AG	Amount	Billion 100 million 10 million million 100 thousand 10 thousand thousand hundred ten yen ¥500,000,000			
	Amount Confirmation (*)	Repayment Date (Note 1)		February 21, 2018	
		(Note 2)			
		Only enter requested account opening method			
	Overdraft (Exclusive Account) Account No.				
Limit No.					

(Request) Only write inside the heavily outlined sections.



Bank-use Only (note 1) If overdraft (exclusive account), repayment date need not be entered (Note 2) Indicate date in four digits.

Transaction Client Code	Approval No.	Item No.	Loan No. (Copy from Execution Voucher)	Supervisor	Verifier	Manager
Ringi No.	Indicate with ○ which is relevant ↓					
	Special	Special (MML)				

Execution Category	New – Renewal	Next Interest Deadline (business day)	MMDDYY
Month end indication code	Other than month end – Month end	Interest Payment Cycle	Lump Sum - months
Holiday adjustment code	Next business day - Prior business day	Deadline Management Category	Own Branch – Center
Interest withdrawal day	day	Next Interest Revision date	MMDDYY – None
Bank base rate	Mizuho TIBOR () months - JBA TIBOR () months - ()		

(*) An objective party other than the operations person is to confirm that there is not discrepancy between the amount on the executed input voucher with seal affixed and the amount on the refund request form.

Mizuho Bank

LEASE AGREEMENT

CONCLUDED BETWEEN

The Unregistered Partnership CALDERARI & SCHWAB, Schloss-Strasse 8a, 2560 Nidau

- Lessor -

AND

STAAR Surgical AG, Hauptstrasse 104, 2560 NIDAU

- Lessee -

1. **Leased property**

The Lessee rents the following spaces in the property Hauptstrasse 104, 2560 Nidau

Office space measuring 150 m², separated into four individual offices with separate entrance area, including two WC on the first floor.

2. **Lease start date**

The lease starts on March 1, 2007.

3. **Lease term**

The lease term is fixed until October 31, 2008.

If the option is not exercised and if neither of the two parties give notice by April 30, 2008, the lease contract will be extended by 1 year, after expiration of the fixed lease term. The notice period is always 6 months and must be adhered to.

3.1 Option right

The Lessee has an option right of 1 x 3 years.

The Lessee must indicate in writing at least 6 months prior whether it elects to exercise its option right.

- 3.2 Every time another lessee vacates a space in the property, the Lessee has the option to move into the vacated space. If the Lessee elects to exercise this option, the Lessee may withdraw from this contract before its expiration as part of the exercised option.

4. Net lease amount

The net lease amount is CHF 21,000.00 annually.

- 4.1 The net lease amount of CHF 21,000.00 annually is tied to the consumer price index BIGA as of March 1, 2007.

After March 1, 2007, the net lease amount may be adjusted once by the full percentage change in the index on each January 1, regardless of the fixed lease term of the contract, at the request of either party. The first adjustment may take place no earlier than January 1, 2008.

4.2 Incidental expenses

Advance payments for heating costs, electricity costs in the common spaces, boiler costs, water charges, waste water and waste removal charges, if any, for which the Lessor will provide an account statement each April 30, amount to CHF 200.00 per month.

The amount charged is based on the leased square meters.

5. Usage of the leased property

- 5.1 The leased property is being used as office space. The Lessee must request the Lessor's approval in the event of any changes to the intended purpose of the space.

5.2. Maintenance

The Lessee is obliged to keep the property clean and in order. Annual repairs that do not exceed 2% of the annual lease amount must borne by the Lessee.

If damage is detected in or on the leased property, the Lessee is required to limit the damage as much as possible, either by taking immediate measures at its own expense or by immediately notifying the Lessor.

The Lessee must permit repairs, minor finishing work or required changes to the leased property and the entire property without claims for compensation.

The Lessee is fully responsible for carrying out the following repair work.

- Repairs of elevator straps, tapes or ropes of shutters and sun shades.
- Replacement of electrical switches, outlets, fuses, light bulbs (also of the lighting fixtures belonging to the building on a pro rata basis), water taps and door locks)
- Unclogging of pipes, sinks, toilets, washing facilities, etc.
- Repair or replacement of seals on radiators or other equipment.

5.3 House regulations

The Lessee undertakes to show reasonable consideration for other lessees and neighbors in every respect and to comply with the applicable house regulations.

5.4 Sub-leasing

Sub-leasing of the spaces is only permitted with the express consent of the Lessor.

5.5 Accessibility of the leased property

The Lessor has the right to enter the leased premises with prior appointment at any time in order to safeguard its interests.

6. Insurances

6.1 The Lessee is expected to reasonably insure all machines, furnishings, furniture, goods and generally all items located in the leased space at its own cost against theft, fire, explosion and water damage, including all risks in connection with its operations, and the Lessee is in particular expected to provide insure cover for tenant liability.
The Lessee is liable for all consequences of potential non-compliance with this obligation with the Lessor being fully compensated.

7. Company signs and lettering

7.1 Installation and execution

The Lessee may only put up company signs and lettering with the prior consent of the Lessor at the indicated location. The Lessor is responsible for deciding its type and design, particularly with regard to the arrangement, order, size, color, format and material.

7.2 Costs

The costs for new lettering or changes must be borne by the Lessee. The Lessee is also responsible for any costs arising from potential removal and reattachment due to a change of lessees.

8. Changes to the leased property

8.1. Approval

Changes to the leased property are only permissible with the express written approval of the Lessor.

9. Return of the leased property

9.1 Cleaning

The leased property must be returned in a clean and generally orderly state.

9.2. Damage

The Lessee is liable for any damage that is not the result of normal wear and tear. Such damage must be repaired by the Lessee by the end of the leasing relationship.

9.3 Repairs

Repairs should be carried out according to the practices of the Property and Home Owners Association (Grund- und Hauseigentümerversand) of Biel and surrounding areas.

10. The Lessee has the right to have the present lease contract entered in the land register at its own cost.

11. Jurisdiction

11.1 The parties agree on Nidau as the jurisdiction in the event of any disputes.

11.2 The Swiss Code of Obligations (Schweizer Obligationenrecht) applies for all liabilities arising under this lease contract.

This contract has been executed in triplicate. One copy each is held by the Lessor and the Lessee and one copy is intended for the land registry office.

The Lessee:

/s/ _____

Philippe Subrin

/s/ _____

Hans Martin Blickensdörfer

STAAR Surgical AG

Nidau, [handwritten] June 11, 2007

The Lessor:

/s/ _____

Walter Schwab

/s/ _____

Enzo Calderari

Unregistered Partnership

CALDERARI & SCHWAB

Nidau,

Subsidiaries of STAAR Surgical Company

Name of Subsidiary	Other Names Under Which it Does Business	State or Other Jurisdiction of Incorporation
STAAR Surgical AG	None	Switzerland
STAAR Japan Inc.	STAAR Japan Godo Kaisha	Japan
STAAR Surgical PTE. LTD	None	Singapore
STAAR Optical Equipment Technology (Shanghai) Co.,	None	China
LTD	None	Spain
STAAR Surgical AG, Sucursal en España	None	Germany
STAAR Surgical AG Niederlassung Germany		

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

STAAR Surgical Company
Monrovia, CA

We hereby consent to the incorporation by reference in the Registration Statements on Form S-3 (No. 333-217888, No. 333-148902, No. 333-143131, No. 333-124022 and No. 333-116901) and Form S-8 (No. 333-213046, No. 333-201232, No. 333-167595 and No. 333-111154) of STAAR Surgical Company of our reports dated February 28, 2018, relating to the consolidated financial statements and financial statement schedule, and the effectiveness of STAAR Surgical Company's internal control over financial reporting, which appear in this Form 10-K.

/s/ BDO USA, LLP

Los Angeles, California
February 28, 2018

CERTIFICATIONS

I, Caren Mason certify that:

1. I have reviewed this annual report on Form 10-K of STAAR Surgical Company;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 28, 2018

/s/ Caren Mason
Caren Mason
*President, Chief Executive Officer and
Director (principal executive officer)*

CERTIFICATIONS

I, Deborah J. Andrews certify that:

1. I have reviewed this annual report on Form 10-K of STAAR Surgical Company;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 28, 2018

/s/ Deborah J. Andrews
Deborah J. Andrews
Chief Financial Officer
(principal accounting and financial officer)

**Certification pursuant to 18 U.S.C. Section 1350,
As adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002**

In connection with the filing of the Annual Report on Form 10-K for the year ended December 29, 2017 (the "Report") by STAAR Surgical Company ("the Company"), each of the undersigned hereby certifies that:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company as of and for the periods presented in the Report.

Dated: February 28, 2018

/s/ Caren Mason
Caren Mason
*President, Chief Executive Officer and Director
(principal executive officer)*

Dated: February 28, 2018

/s/ Deborah J. Andrews
Deborah J. Andrews
*Chief Financial Officer
(principal financial officer)*

A signed original of this statement has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.
