STAAR SURGICAL CO
Form 10-K
February 21, 2019

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 28, 2018

Or

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from to

Commission file number: 0-11634

STAAR SURGICAL COMPANY

(Exact name of registrant as specified in its charter)

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

1911 Walker Avenue

Monrovia, California 91016

(Address of principal executive offices)

(626) 303-7902

(Registrant's telephone number, including area code)

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

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

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

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

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 every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405 of this chapter) 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 an 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.

Large accelerated filer	Accelerated filer
Non-accelerated filer	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 Exchange 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 29, 2018, the last business day of the registrant's most recently completed second fiscal quarter, was approximately $1,298,148,179 based on the closing price per share of $31.00 of the registrant's Common Stock on that

date.

The registrant has 44,208,157 shares of common stock, par value $0.01 per share, issued and outstanding as of February 18, 2019.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement relating to its 2019 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

TABLE OF CONTENTS

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,” “should,” “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. We have been dedicated solely to ophthalmic surgery for over 30 years. 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.

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 13. The reader may also find it helpful to refer to the discussion of the structure and function of the human eye that begins on page 6.

Operations

STAAR has significant operations globally. Activities outside the United States (U.S.) accounted for 94% of our total sales in fiscal year 2018, 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, Spain, the U.S., 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 countries where we sell.

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 offices 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. STAAR also operates a Technology Center housing its Research & Development team and labs in Tustin, California. Most recently, STAAR opened a facility in Lake Forest, California for executive and corporate offices and the expected future manufacturing of its Presbyopia lenses.
- 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 900,000 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 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. 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. The Toric ICL (TICL), which also corrects for astigmatism, 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 4.0 million refractive procedures, primarily laser vision procedures, were performed worldwide in 2018. 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 lens-based refractive procedure (unlike LASIK) with over 900,000 ICLs implanted to date. Surgeons have published over 100 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 and participate in major ophthalmic conventions around the world and invest in market development, practice support, 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 ICL 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. In December 2017, the EVO+ was approved for marketing and sales in India and Canada. In September 2018, the FDA granted approval of our PMA Supplement for the Visian Toric ICL for the correction of myopia with astigmatism for marketing and sale in the United States. In early 2018, we commenced a multi-site clinical trial to support CE Mark approval of a claim that our EVO+ Visian ICL with aspheric (EDOF) optic corrects/reduces 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 82% of our total sales in fiscal 2018, 75% of our total sales in fiscal 2017 and 72% of our total sales in fiscal 2016.

Other Products

Intraocular Lenses (IOLs). We produce and market a line of foldable IOLs 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. In most of the countries where STAAR does business, government agencies reimburse most or all of the cost of cataract surgery and IOLs.

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 13% of our total sales in fiscal 2018, 19% of our total sales in fiscal 2017 and 24% of our total sales in fiscal 2016.

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 5% of our total sales in fiscal 2018, 6% of our total sales in fiscal 2017 and 4% of our total sales in fiscal 2016.

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 28, 2018, we owned approximately 62 United States and foreign patents and had 24 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 on a quarterly basis, 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, Spain, the U.S., 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 37% of our consolidated net sales during fiscal 2018. Shanghai Langsheng sells into China and Hong Kong. Sales for fiscal 2017 and 2016 also reflect the sales into Hong Kong so as to be comparable to fiscal 2018 presentation. 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
2018	$ 46,070	37.2 %
2017	$ 24,473	27.0 %
2016	$ 16,624	20.2 %

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), Bausch Health Companies (formerly Valeant, 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 two principal types of phakic IOLs are (1) posterior chamber designs like the ICL, and (2) iris clip anterior chamber PIOLs like the Artisan® and Artiflex® lenses made by Ophtec. 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 Bausch Health Companies) combined accounting for approximately 60% of total market revenue, according to a 2018 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, China, Europe, Japan, Korea and the U.S., 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 ICLs and IOLs are Class III devices subject to the PMA approval process and not 510(k) clearance. The more rigorous PMA process requires us to demonstrate that a new medical device is safe and effective for its intended use. The FDA may require that a PMA 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 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, 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. On November 14, 2014 and continuing through February 4, 2015, the FDA again 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). 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. On April 30, 2018 continuing through May 18, 2018 FDA again inspected our Monrovia facility, and on June 19, 2018, we received a close-out letter from the FDA lifting the 2014 Warning Letter.

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.

During 2019, we intend to continue our focus on research and development in the following areas:

- Development of presbyopia-correcting ophthalmic lenses, including models that correct sphere and cylinder, including clinical trials of the same;
- 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 28, 2018, we had approximately 475 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 SEC 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 aluminium garnet crystals (Nd:YAG) generate a high-energy beam that can be used in a number of ophthalmic procedures, including creating iridotomies before implantation of some models of the ICL.

ITEM 1A. Risk Factors

Investment in our securities involves a high degree of risk. Investors should carefully consider the following risk factors, in addition to other information contained in this report before making a decision to invest in our common stock. These risks are not the only ones we face. These risks and uncertainties, as well as other risks that we cannot foresee at this time, have the potential to affect our business, financial condition, results of operations, cash flows, strategies and prospects in a material and adverse manner. The trading price of our common stock could decline due to any of these risks, and investors may lose all or part of their investment. This Annual Report on Form 10-K contains forward-looking statements that involve risks and uncertainties. Actual results could differ materially from those anticipated or implied in these forward-looking statements because of factors beyond our control, including the risks faced by us described below.

Risks Related to Our Business

We may not be able to continue our growth and profitability trajectory.

In 2018 our revenue grew by 37% and we achieved $0.11 diluted earnings per share. While we plan to continue sales growth and remain profitable, there can be no guarantee that we will achieve our growth and profitability plans in 2019. We have reported losses in four of the past five years. Our profitability is challenged by the competitive nature of our industry and the other risks to our business detailed herein.

Compliance issues may adversely impact our operations.

Quality system and other deficiencies observed by the FDA at certain of our facilities in the past resulted in delays in product approvals. We plan to remain in compliance with regulatory requirements established by applicable global regulatory agencies, however, there can be no guaranty that we will do so. If we cannot maintain compliance with a particular jurisdiction’s regulatory requirements, it could adversely impact our financial performance/ have a material adverse effect on our ongoing business and operations. We expect to continue to devote resources and attention to our quality systems and compliance and other regulatory requirements 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 materially and adversely impact our business and operations.

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 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 37% of our fiscal 2018 consolidated net sales, ceased to serve as our distributor, or significantly underperformed our expectations, we may experience a substantial reduction in sales.

Unfavorable economic conditions or negative publicity concerning complications of laser eye surgery, or medical devices in general, could hurt sales of our refractive products.

Approximately eighty-two (82%) of our revenue was derived from ICL lenses used in 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. Recent negative publicity regarding alleged harm to patients caused by medical device manufacturers may decrease patient interest in undergoing a medical procedure involving a medical device such as our ICL.

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 production could be delayed and 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-containing raw material used in our ICLs and IOLs internally. If the supply of these collagen-containing 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 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. For example, in 2018 our ICL sales grew 48%. If our suppliers or we are unable or our suppliers are unwilling to meet our increased 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.

Because our business is global our sales and profits may fluctuate or decline in response to changes in foreign currency exchange rates and/or other international risks (including tariffs).

Activities outside the U.S. accounted for approximately 94% of our total sales during 2018. 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 we incur some of our sales and expenses in currencies other than the U.S. dollar. Our most significant currency exposures are to the Japanese yen, the euro, and the Swiss franc, and the exchange rates between these currencies and the U.S. dollar may fluctuate substantially. We do not actively hedge our exposure to currency rate fluctuations. The strengthening of the U.S. dollar would likely negatively impact our results. 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, including, enjoying less stringent protection of intellectual property, and facing economic, political, and social uncertainty in some countries, especially in emerging markets. 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 our sales, including as a result of the imposition of tariffs or other barriers or restrictions on trade, or increase our costs. The institution of trade tariffs both globally and between the U.S. and China specifically could negatively impact the overall economic condition in our markets, including China, which could have a negative effect on our 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. 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, financial condition and results of operations as a whole.

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

We have accumulated approximately $135.0 million of U.S. federal tax net operating loss carryforwards as of December 28, 2018, which can be used to offset taxable income in future quarters if our U.S. operations become profitable. If unused, the pre-2018 tax loss carryforwards will begin to expire between 2020 and 2038. 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. Our ability to utilize any future net operating losses may also be limited by the recently enacted legislation commonly known as the Tax Cuts and Jobs Act of 2017, or the Tax Act. Under the Tax Act, the amount of post-2017 net operating losses that we are permitted to deduct in any taxable year is limited to 80% of our taxable income in such year. The unused net operating losses, pre-2018 tax year can still offset 100% of taxable income. In addition, the Tax Act generally eliminates the ability to carry back any net operating loss to prior taxable years, while allowing post-2017 unused net operating losses to be carried forward indefinitely. Due to these changes under the Tax Act, we may not be able to realize a tax benefit from the use of our net operating losses, whether or not we generate profits in future years. Moreover, if we were to experience a significant change in ownership, Internal Revenue Code Section 382 may restrict the future utilization of our tax loss carryforwards even if our U.S. operations generate significant profits.

We are vulnerable to any loss of use of our principal manufacturing facility.

We manufacture most of our products at a single facility in Monrovia, California. All or a portion of the 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. Developing additional manufacturing sites may require significant expense for personnel and equipment and a long period to obtain regulatory approvals. Our California and Japanese facilities are in areas where earthquakes could cause catastrophic loss.

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. For example, we have commenced activities to resume manufacturing ICLs at our Swiss facility, but there can be no guaranty whether or when that facility will be prepared and approved by regulators for manufacturing. 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, financial condition and results of operations.

If any or a portion 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 and shipments, delay or reduce sales 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 cover any particular loss, or, if covered, be sufficient. 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 primary competitors, including Novartis (formerly Alcon), Johnson & Johnson (formerly Abbott Medical Optics, or AMO) and Bausch Health Companies (formerly Valeant or Bausch & Lomb), have much greater financial, technical, marketing and distribution resources and brand name recognition 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. With our increased commercial success with the ICL, other companies may seek to enter the refractive phakic intraocular lens market.

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 U.S. 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, business, financial condition and results of operations. Our reliance on foreign subsidiaries and independent distributors requires 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. Despite precautions we may take, non-compliance may occur that could harm our reputation and financial results. 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 not be covered, 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 investors 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 $5.3 million ($1.6 million for the Japan Plan and $3.7 million for the Swiss Plan) as of December 28, 2018.

If our cash flow from operations is insufficient to fund our worldwide pension obligations, as well as other cash requirements, 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 and use of an irradiator. 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 financial condition and results of operations. If we were involved in an environmental accident or found to be in substantial non-compliance with applicable environmental laws, it could harm our reputation, and we could be held liable for damages or penalized with fines.

Data corruption, cyber-based attacks or network security breaches and/or noncompliance with data protection regulations could negatively impact our operations.

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 gain access to our systems or facilities, and may, among other things, prevent access to our systems. 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. For example, while we maintain cyber insurance, it may be insufficient to address any potential loss incurred.

We are subject to various data protection regulations in different jurisdictions, including the General Data Protection Regulation (Regulation (EU) 2016/679) (GDPR) and the California Consumer Privacy Act of 2018. We have made and continue to engage in compliance efforts to satisfy these regulations, however, we may be unsuccessful in complying with applicable requirements, and may be at risk of enforcement actions and/or subject to fines, including those imposed by a data protection authority. As a result, we may incur substantial expense in complying with data protection regulations, exposure resulting from a data breach, ransomware or non-compliance and may be distracted from other aspects of our business.

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 poses risks to our business and 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 payments or 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. Acquisitions may also divert management’s attention from our core business. 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.

If we are not able to manage growth successfully, this could adversely affect our business, financial condition, and results of operations.

If we continue to experience rapid growth, this places a significant strain on financial, operational, and managerial resources. We must continue to implement and enhance our managerial, operational and financial systems, expand our operations, and continue to recruit and train qualified personnel. There can be no assurance that our strategic and operational planning will allow us to adequately manage anticipated growth. In addition, the expense associated with increased manufacturing and sales/marketing to meet increased demand may exceed our expectations. Any inability to successfully manage growth could materially and adversely affect our business, financial condition, and results of operation.

Risks Related to the Ophthalmic Products Industry

Unless we keep pace with advances in our industry and persuade physicians to adopt our new products, our sales will not grow and may decline.

Our future growth depends, in part, on our ability to timely 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 are 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 research and development or technologies that do not lead to better products, more effective or advanced products could surpass our current and planned products. In addition, such product development efforts could require a significant investment of resources. If we are able to develop new products, we must manufacture these products economically and market them successfully by demonstrating to enough eye-care professionals the overall benefits of using them. If we do not timely develop new products that meet market demand or if there is insufficient demand for our new products, our sales and results of operations could be harmed. For example, it is uncertain whether physicians in the U.S. will adopt the Visian ICL for the correction of myopia and astigmatism, which the FDA approved for marketing and sale in the U.S. in September 2018.

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 developing, including those currently in development, may not complete the development process or obtain the regulatory approvals required for us to successfully market the products. Our new products, including those currently under development, may fail to become commercially successful.

We may be required to conduct extensive clinical trials to demonstrate safety and efficacy of new or enhanced products, such clinical trials are expensive, complex, can take years to complete, and have highly uncertain outcomes.

In order to further advance the development of, and ultimately receive regulatory approval to manufacture and sell, our new products or product enhancements, we may be required to conduct extensive clinical trials to demonstrate their safety and efficacy to the satisfaction of the FDA or regulatory authorities in other countries. Clinical trials are expensive, complex, can take many years to complete, and have highly uncertain outcomes. Delays, setbacks, or failures can occur at any time, or in any phase of the clinical trials, and can result from concerns about safety, a lack of demonstrated efficacy, or poor study or trial design. For example, we cannot ensure that our on-going clinical trial of the EVO Visian ICL with EDOF optic will succeed in obtaining a claim for correcting early presbyopia. The commencement and completion of clinical trials may be delayed or prevented by many factors, including, but not limited to:

- an inability to reach agreement with regulatory authorities regarding the scope or extent of a proposed clinical trial;
- an inability to timely identify and reach agreement on acceptable terms with prospective clinical trial sites and entities involved in the conduct of our clinical trials;
- failure by third-party clinical trial managers to comply with applicable regulations or protocols;
- flaws in the design of the clinical trials;
- slower than expected rates of patient recruitment and enrollment;
- periodic amendments to clinical trial protocols to address certain variables which arise during the course of a trial;
- lack of effectiveness of our products; or
- unforeseen safety issues.

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. Failure to receive necessary approvals in foreign jurisdictions on a timely basis, or at all, could harm our business and operating results. In addition, regulations and requirements for approvals can vary in each international country, which can significantly increase the costs to sell our products in these international countries.

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. Furthermore, there is no assurance that clearance or approval will be granted.

If a regulatory authority delays or does not grant 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 expensive 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, cause the loss of previously received approvals or clearances or impact our ability to modify our currently cleared products on a timely basis.

We depend on proprietary technology but our intellectual property protections may be limited.

While we rely on patents, trademarks, trade secrecy laws, contractual provisions and confidentiality procedures and copyright laws to protect the proprietary aspects of our technology, we rely more on trade secrets and know-how, which may not prevent third parties from using publicly available information to access our technology. With respect to our patents, any of them 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 technology. Litigation may be necessary to enforce our intellectual property rights, and to protect or determine the validity and scope of our proprietary rights. We also challenge others' patents or patent applications from time to time. 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 or instituted by us, whether or not successful, could result in substantial costs, divert resources and the efforts of our personnel away from daily operations, harm our reputation, result in the impairment of our intellectual property rights, limit our ability to pursue future products and/or otherwise materially

adversely impact our business.

We may not successfully replace our existing products, including those that lose or have lost patent protection.

As our existing patents expire, many of which already 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.

While we will continue developing intellectual property protections for our future products, third parties may pursue blocking patents that limit our ability to manufacture such products.

We plan to continue relying on patents, trade secrets and other intellectual property rights to protect products and technology that we may develop or employ in the future, but third parties may develop and obtain patents covering such products or technology. In such event, we may need to obtain licenses for such patents. However, we may not be able to obtain licenses on reasonable terms, if at all, which could limit our ability to manufacture our future products and operate our business.

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, because many 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 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 or approved by regulatory authorities prior to distribution. If recalled products have already been implanted, we may bear some or all of the cost of corrective surgery. Recalls may also damage our professional reputation and the reputation of our products. The inconvenience caused by recalls and related interruptions in supply, the underlying causal issues, and the damage to our reputation, could cause professionals to discontinue using our products.

Companies are required to maintain certain records of actions, even if they determine such actions are not reportable to the FDA 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. 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.

Changes in FDA or international regulations related to product approval, including those that apply retroactively, could make us less competitive and harm our business.

FDA and foreign regulations depend heavily on administrative interpretation, and we cannot assure investors 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 and financial condition 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.

If we modify our products, we may have to obtain new marketing clearances or approvals, or may have 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.

Our 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.

The market price for our common stock has fluctuated widely. The closing price of our common stock ranged from $13.95 to $50.65 per share during the year ended December 28, 2018. 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 the business and 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 a 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 our 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 purchase 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 our 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 our 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 our 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;
- stockholders cannot fill vacancies on our Board of Directors;
- certain provisions, including those related to changing the number of directors, limiting our stockholders' ability to fill vacancies on our Board of Directors, prohibiting stockholder action by written consent, and amending such provisions, cannot be altered, amended or repealed, and provisions inconsistent therewith cannot be adopted, without the affirmative vote of holders of at least two-thirds in voting power of our outstanding shares of common stock entitled to vote thereon; 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.

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 common stock price to decline.

Our largest investor beneficially owns approximately 24% of our outstanding common stock, and our largest four investors beneficially own approximately 48% of our outstanding common stock. Three of our current five directors were recommended by our investors. The sale of a substantial number of shares of our common stock by any or all of our largest investors or our other stockholders within a short period of time could cause our common 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.

In addition, 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.

Future sales of our common stock could reduce our stock price.

We could issue additional shares of common or preferred stock to raise additional capital or for other corporate purposes without stockholder approval. In addition, we could designate and sell a class of preferred stock with preferential rights over our 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 is available to cover the future public offering and sale of up to approximately $127,000,000 in equity or debt securities or any combination of such securities. Sales of our 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.

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. For example, in May 2018, we leased a facility in Lake Forest, California with office and manufacturing capabilities.

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.”

Holders

As of February 19, 2019, there were approximately 323 record holders of our Common Stock.

Dividends

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

Stock Performance Graph

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

The following graph shows a comparison from January 3, 2014 to December 28, 2018 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 January 3, 2014 in STAAR common stock and in each of the composite indices, and that dividends (if any) were reinvested. We have never paid dividends on our common stock and have no present plans to do so.

Total Returns Index for Fiscal Years:	2013	2014	2015	2016	2017	2018
STAAR Surgical Company	100.00	56.09	44.35	67.39	96.28	194.17
The Nasdaq Stock Market (US and Foreign Companies)	100.00	115.43	123.71	134.59	145.94	140.56
Peer Group	100.00	111.33	130.12	170.32	225.93	212.33

Notes:

A. The lines represent monthly index levels derived from compounded daily returns that include all dividends.
B. These indexes are reweighted daily, using the market capitalization from the previous trading day.
C. If the monthly interval, based on the fiscal year-end, is not a trading day, the preceding trading day is used.
D. The index level for all series was set to $100.00 on January 3, 2014.

ITEM 6. Selected Financial Data

The following table sets forth selected consolidated financial data with respect to the five most recent fiscal years ended December 28, 2018, December 29, 2017, December 30, 2016, January 1, 2016 and January 2, 2015. The selected Consolidated Statement of Operations data set forth below for each of the three most recent fiscal years, and the selected Consolidated Balance Sheet data set forth below at December 28, 2018 and December 29, 2017 are derived from our Consolidated Financial Statements, which have been audited by BDO USA, LLP, our independent registered public accounting firm, as indicated in their report included in this Annual Report. The selected Consolidated Statement of Operations data set forth below for each of the two fiscal years in the periods ended January 1, 2016 and January 2, 2015 and the Consolidated Balance Sheet data set forth below at December 30, 2016, January 1, 2016 and January 2, 2015 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 28, 2018[1]	December 29, 2017[1]	December 30, 2016[1]	January 1, 2016[1]	January 2, 2015[1]
	(In thousands except per share data)				
Statement of Operations					
Net sales	$123,954	$ 90,611	$ 82,432	$ 77,123	$ 74,987
Cost of sales	32,444	26,331	24,063	24,400	26,164
Gross profit	91,510	64,280	58,369	52,723	48,823
General and administrative	24,287	19,465	21,671	18,840	18,238
Marketing and selling	38,600	28,402	28,685	23,970	25,897
Research and development	22,028	20,044	20,668	15,250	12,394
Other general and administrative expenses	—	—	—	—	321
Operating income (loss)	6,595	(3,631)	(12,655)	(5,337)	(8,027)
Total other income (expense), net	44	1,335	211	(268)	(618)
Income (loss) before income taxes	6,639	(2,296)	(12,444)	(5,605)	(8,645)
Income tax provision (benefit)	1,671	(157)	(315)	928	(253)
Net income (loss)	$4,968	$ (2,139)	$ (12,129)	$ (6,533)	$ (8,392)
Net income (loss) per share:					
Basic	$0.12	$ (0.05)	$ (0.30)	$ (0.17)	$ (0.22)
Diluted	$0.11	$ (0.05)	$ (0.30)	$ (0.17)	$ (0.22)
Weighted average shares outstanding:					
Basic	42,587	41,004	40,329	39,260	38,091
Diluted	45,257	41,004	40,329	39,260	38,091
Balance Sheet Data					
Working capital	$123,844	$ 34,802	$ 28,450	$ 31,117	$ 28,231
Total assets	167,339	67,932	65,443	62,382	58,278
Long-term obligations	7,185	5,908	6,471	6,019	5,109
Stockholders' equity	132,426	42,936	37,905	38,846	37,099

[1] The Company adopted ASU 2014-09, "Revenue from Contracts with Customers (Topic 606)" in fiscal 2018 using the modified retrospective method. As such, fiscal 2014 through 2017 are presented under the previous revenue recognition standard, i.e. ASC 605.

27

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," "should," "forecast" and similar expressions in connection with any d 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 EVO family of lenses in the U.S.); commercialization of new or improved products; future economic conditions or size of market opportunities; expected costs of quality system remediation efforts; statements of belief, including as to achieving 2019 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 2019

For 2019, we intend to continue achieving and strengthening our 2018 strategic priorities, which are as follows:

- 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

To realize these priorities, we are planning to:

- Make initial investments in manufacturing and facilities expansion that include, among other things: (i) increasing manufacturing capacity at our Monrovia, California facility for our Myopia ICLs; (ii) reopening and expanding our manufacturing and distribution facilities in Nidau, Switzerland; (iii) preparing for the validation of our Lake Forest, California facility for the manufacturing of our ICL with EDOF for presbyopia lenses expected to be approved for sale initially in CE Mark countries;
- Continue market share gains in all global markets, including China. We will continue to focus on increasing consideration and usage of low and mid-diopter ICLs;
- Increase investment in Direct-to-Consumer marketing and patient education in targeted markets; and
- Strengthen existing and finalize new Strategic Agreements and Alliances with global partners. While each of these agreements is typically not in and of itself significant to our business, they have become the way we do business with certain customers, and they demonstrate a customer's commitment to our product. At times we issue a press release regarding a finalized agreement, largely at the customer's request, for the customer's benefit in their market. For example, several of the clinics in the Smile Eyes group formalized their relationship with a recently announced Strategic Cooperation Agreement.

We believe that if we accomplish our plans, we will achieve the following target results for 2019:

- ICL unit growth percentage target increase of 30% or above compared with 2018 ICL unit growth;
- Overall revenue growth percentage target increase of 20% over 2018 (despite an overall sales decline in our Other Products segment of approximately $3.6 million, including an approximately $2.6 million reduction in sales of low margin injector parts);
- GAAP Net Income is anticipated to increase over 2018; and
- Positive full year cash flow and cash balance increase.

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		
	2018	2017	2016
Net sales	100.0%	100.0%	100.0%
Cost of sales	26.2 %	29.1 %	29.2 %
Gross profit	73.8 %	70.9 %	70.8 %
General and administrative	19.6 %	21.5 %	26.3 %
Marketing and selling	31.1 %	31.3 %	34.8 %
Research and development	17.8 %	22.1 %	25.0 %
Total selling, general and administrative	68.5 %	74.9 %	86.1 %
Operating income (loss)	5.3 %	(4.0)%	(15.3)%
Total other income, net	0.0 %	1.5 %	0.2 %
Income (loss) before income taxes	5.3 %	(2.5)%	(15.1)%
Provision (benefit) for income taxes	1.3 %	(0.2)%	(0.4)%

Net income (loss)	4.0 %	(2.3)%	(14.7)%

Net Sales

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

	2018			2017			2016		
	% of Total		Sales	% of Total		Sales	% of Total		Sales
ICLs	81.5	%	$101,082	75.4	%	$68,325	71.7	%	$59,111
Other product sales									
IOLs	13.1	%	16,193	19.0	%	17,258	23.9	%	19,706
Other surgical products	5.4	%	6,679	5.6	%	5,028	4.4	%	3,615
Total other product sales	18.5	%	22,872	24.6	%	22,286	28.3	%	23,321
Net sales	100.0	%	$123,954	100.0	%	$90,611	100.0	%	$82,432

Net sales for 2018 were $124.0 million, a 37% increase over the $90.6 million reported in fiscal 2017. The increase in net sales was due to increases in ICL sales of $32.8 million and other product sales of $0.6 million. Changes in foreign currency favorably impacted net sales by $0.2 million.

Net sales for 2017 were $90.6 million, a 10% 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, partially offset by a decrease in other product sales of $1.0 million. Changes in foreign currency unfavorably impacted net sales by $0.5 million.

Total ICL sales for 2018 were $101.1 million, a 48% increase from $68.3 million reported for fiscal 2017, with unit growth up 54%. The sales increase was driven by the APAC region, which grew 73% with unit growth of 82%, primarily due to sales growth in China up 91%, Japan up 90%, and Korea up 37%. The Europe region, grew 20% with unit growth of 12%, primarily due to increased sales in Germany up 31%, Distributor Operations up 21% and Spain up 13%. The Middle East and Latin America region increased 19%, with unit growth of 12% due to increased sales in both the Middle East and Latin America. The North America region grew 4%, with unit growth of 6%, primarily due to growth in Canada. In November 2018, the U.S. started to sell Toric ICLs. Changes in foreign currency favorably impacted ICL sales by $0.1 million. ICL sales represented 81.5% of our total sales for fiscal year 2017.

Total ICL sales for 2017 were $68.3 million, a 16% increase from $59.1 million reported for fiscal 2016, with unit growth up 17%. The sales increase was driven by the APAC region, which grew 23% with unit growth of 25%, primarily due to sales growth in China up 48%, Japan up 35%, and APAC distributor markets up 24%, partially offset by decreased sales in Korea of 26%. The Europe region, grew 12% with unit growth of 11%, primarily due to increased sales in Germany up 15%, Distributor Operations up 12% and Spain up 9%. The Middle East and Latin America region declined 1%, with unit growth of 1% due to decreased sales in Latin America offset by sales in the Middle East. The North America region grew 2% and units grew 1%. 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.

Other product sales, including IOLs were $22.9 million for fiscal 2018, an increase of 2.6% from $22.3 million reported in fiscal 2017. The increase is due to an increase in preloaded injector part sales to a third-party manufacturer for product they sell to their customers, offset by a decrease in IOL sales. Changes in foreign currency favorably impacted other product sales by $0.1 million. Other product sales represented 18.5% of our total sales for fiscal year 2018.

Other product sales, including IOLs were $23.3 million for fiscal 2017, a decrease of 4.4% from $23.3 million reported in fiscal 2016. The decrease is 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, offset by an increase in preloaded injector part sales to a third-party manufacturer for product they sell to their customers. Changes in foreign currency unfavorably impacted other product sales by $0.4 million. Other product sales represented 24.6% of our total sales for fiscal year 2017.

Gross Profit

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

				Percentage Change	
				2018 vs.	2017 vs.
	2018	2017	2016	2017	2016
Gross profit	$91,510	$64,280	$58,369	42.4%	10.1%
Gross margin	73.8 %	70.9 %	70.8 %		

Gross profit for 2018 was $91.5 million, a 42.4% increase compared to the $64.3 million reported for 2017. Gross profit margin increased to 73.8% of revenue for 2018 compared to 70.9% of revenue for 2017, due to favorable product mix, lower unit costs as a result of significantly increased production volumes, to support the 47.9% growth in ICL sales, resulting in better overhead absorption, and lower inventory provisions and freight costs, partially offset by the effect of lower average selling prices.

Gross profit for 2017 was $64.3 million, a 10.1% increase compared to the $58.4 million reported for 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.

General and Administrative Expense

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

				Percentage Change	
				2018 vs.	2017 vs.
	2018	2017	2016	2017	2016
General and administrative expense	$24,287	$19,465	$21,671	24.8%	(10.2)%
Percentage of sales	19.6 %	21.5 %	26.3 %		

General and administrative expenses for 2018 were $24.3 million, an increase of 24.8% when compared with $19.5 million reported for 2017. The increase in general and administrative expenses was due to an increase in headcount and salary-related expenses including stock-based compensation, and increased facility costs.

General and administrative expenses for 2017 were $19.5 million, a decrease of 10.2% when compared with $21.7 million reported for 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.

Marketing and Selling Expense

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

				Percentage Change	
				2018 vs.	2017 vs.
	2018	2017	2016	2017	2016
Marketing and selling expense	$38,600	$28,402	$28,685	35.9%	(1.0)%
Percentage of sales	31.1 %	31.3 %	34.8 %		

Marketing and selling expenses for 2018 were $38.6 million, an increase of 35.9% when compared with $28.4 million for 2017. The increase in marketing and selling expenses was due to an increase in headcount and salary-related expenses including stock-based compensation and investments in digital, consumer, and strategic marketing and commercial infrastructure.

Marketing and selling expenses for 2017 were $28.4 million, a decrease of 1.0% when compared with $28.7 million for 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.

Research and Development Expense

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

				Percentage Change	
				2018 vs.	2017 vs.
	2018	2017	2016	2017	2016
Research and development expense	$22,028	$20,044	$20,668	9.9%	(3.0)%
Percentage of sales	17.8 %	22.1 %	25.0 %		

Research and development expenses for 2018 were $22.0 million, an increase of 9.9% compared to $20.0 million for 2017. The increase was due to an increase in headcount and salary-related expenses including stock-based compensation, increased clinical expenses associated with our clinical trial for the next generation ICL with an EDOF optic, and an increase in medical affairs expenses.

Research and development expenses for 2017 were $20.0 million, a decrease of 3.0% compared to $20.7 million for 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 consists primarily of compensation and related costs for personnel responsible for the research and development of new and existing products, the regulatory and clinical activities required to acquire and maintain product approvals globally and medical affairs expenses. 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):

				Percentage Change	
				2018 vs.	2017 vs.
2018	2017	2016		2017	2016

Other income, net	$44	$1,335	$211	(96.7)%	—*
Percentage of sales	0.0 %	1.5 %	0.2 %		

*Denotes change is greater than +100%.

Other income for 2018, 2017 and 2016 was $0.0 million, $1.3 million, and $0.2 million, respectively. The decrease in 2018 was mainly due to losses on foreign currency transactions compared to gains in 2017, partially offset by a net increase in interest income due to higher cash balances. The increase in 2017 was mainly due to gains on foreign currency transactions compared to losses in 2016.

Other income, net generally relates to interest income earned on cash and cash equivalents, 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, net (in thousands).

	Favorable (Unfavorable)	
	2018 vs. 2017	2017 vs. 2016
Interest income, net	$277	$—
Foreign exchange	(1,655)	966
Royalty income	52	(37)
Other	35	195
Net change in other income (expense), net	$(1,291)	$1,124

Provision (Benefit) for Income Taxes

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

	2018	2017	2016	Percentage Change 2018 vs. 2017	Percentage Change 2017 vs. 2016
Provision (benefit) for income taxes	$1,671	$(157)	$(315)	—*	(50.2)%

*Denotes change is greater than +100%.

We recorded income taxes for 2018 as a result of income tax expense generated primarily from profits in our Swiss and Japan operations and U.S. withholding taxes on those profits. We recorded a benefit from income taxes for 2017 due primarily to a U.S. income tax benefit related to an alternative minimum tax (AMT) carryforward, offset by income tax expense generated from profits in our Swiss and Japan operations. The benefit from income taxes in fiscal 2016, was primarily due to 1) net operating losses reported by our foreign operations due principally 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 our foreign subsidiaries effective April 1, 2016. During 2018, 2017 and 2016, there are no unrecognized tax benefits related to uncertain tax positions taken by us.

All earnings from our subsidiaries are not considered to be permanently reinvested. Accordingly, we provide withholding and U.S. taxes on all unremitted foreign earnings. During 2018, 2017 and 2016 there were no withholding taxes paid to foreign jurisdictions.

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. Key provisions that could have an impact on our Consolidated Financial Statements are the deemed repatriation of foreign earnings, the remeasurement of certain net deferred assets and other liabilities for the change in the U.S. corporate tax rate from 35 percent to 21 percent, and the elimination of the AMT.

We applied the guidance in SAB 118 when accounting for the enactment-date effects of the 2017 Tax Act and throughout 2018. At that time, for 2017, we made reasonable estimates of the impact and included $5.7 million in foreign earnings, which were fully offset by the deemed foreign tax credit. This inclusion amount was later finalized at $7.5 million. At December 28, 2018, we have now completed our accounting for all the enactment-date income tax effects of the 2017 Tax Act.

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. We expect to receive a refund of $0.3 million of this AMT credit with the filing of our 2018 U.S. federal tax return.

Beginning in 2018, the 2017 Tax Act subjects a U.S. shareholder to tax on Global Intangible Low Tax Income ("GILTI") earned by certain foreign subsidiaries. In January 2018, the FASB released guidance (Staff Q&A Topic 740, No. 5) on the accounting for tax on the GILTI provisions of the 2017 Tax Act. In general, GILTI is the excess of a U.S. shareholder's total net foreign income over a deemed return on tangible assets. The provision further allows a deduction of 50 percent of GILTI, however this deduction is limited by our pre-GILTI U.S. income. For 2018, we included GILTI of $7.7 million in U.S. gross income, which was fully offset with net operating loss carryforwards.

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. In evaluating our 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, we begin with historical results and incorporate 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 we use to manage the underlying businesses. In evaluating the objective evidence that historical results provide, we consider 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.

Due to our history of losses in the U.S., the valuation allowance has fully offset the value of U.S. deferred tax assets on our balance sheet as of December 28, 2018, with the exception of the remaining refundable alternative minimum tax credit of $0.3 million. However, as a result of GILTI, we have reported income in the U.S. in 2018 for the first time in many years. As our global profitability improves, including our ability to meet or exceed forecasts, and as this global profit is now includable in U.S. income under GILTI, we will continue to reassess at each reporting period the need for a full or partial valuation allowance on our U.S. net deferred tax assets. If we determine based upon all available positive or negative evidence that it is more likely than not that the deferred tax asset is realizable, we would record an income tax benefit for all or a portion of the valuation allowance in the period in which such determination is made. Any such changes in the assessment of a full or partial valuation allowance could have a material impact on earnings. The valuation allowance was $43.1 million as of December 28, 2018.

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

On August 10, 2018, we closed an offering of our common stock. As part of this transaction, we issued 1,999,850 shares of common stock at a price of $36.309 per share. Net proceeds, after deducting expenses, received from this offering were $72,150,000. We intend to use the net proceeds of this offering to fund operations, which may include advancing and broadening commercialization of our ICL family of products, funding pipeline research and development activities and clinical trials, funding incremental investments in automation and precision manufacturing, and capital expenditures, such as information systems, and for general corporate purposes, including working capital. We have not yet determined the amounts on any of the areas listed above or the timing of these expenditures. We invest the net proceeds in short-term interest-bearing obligations, investment-grade instruments, certificates of deposit or direct or guaranteed obligations of the U.S. government.

We believe our current cash balances coupled with cash flows from operating activities is expected to be adequate to cover our operational and business needs through at least the next 12 months from the issuance of this Annual Report. Our financial condition at December 28, 2018, December 29, 2017 and December 30, 2016 included the following (in millions):

				2018 vs. 2017	2017 vs. 2016
	2018	2017	2016		
Cash and cash equivalents	$103.9	$18.5	$14.0	$85.4	$4.5
Current assets	$151.6	$53.9	$49.5	$97.7	$4.4
Current liabilities	27.7	19.1	21.0	8.6	(1.9)
Working capital	$123.9	$34.8	$28.5	$89.1	$6.3

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

Net cash provided by operating activities was $12.8 million, $2.9 million and $1.0 million for 2018, 2017 and 2016, respectively. For 2018, net cash provided by operating activities consisted of $12.3 million in non-cash items and $5.0 million in net income, offset by $4.5 million in working-capital changes. For 2017, net cash provided by

operating activities consisted of $9.0 million in non-cash items, offset by $4.0 million in working-capital changes and a $2.1 million net loss. 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.

Net cash used in investing activities was $2.2 million, $1.0 million and $3.2 million, for 2018, 2017 and 2016 respectively, and relate primarily to the acquisition of property, plant, and equipment. The increase in investment in property, plant and equipment during 2018, relative to 2017, is primarily due to continued increased investments in manufacturing and quality system improvement projects. 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.

Net cash provided by financing activities was $74.6 million, $2.4 million and $3.0 million for 2018, 2017 and 2016, respectively. Net cash provided by financing activities resulting primarily from the proceeds of $72.2 million from the equity offering, as discussed above. In addition, the increase also consisted of $5.2 million of proceeds from the exercise of stock options offset by $1.9 million repayment of capital lease obligations and $0.7 million repayment on the Japan line of credit. 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.

Accounts receivable, net was $25.9 million and $20.0 million at December 28, 2018 and December 29, 2017, respectively. Days' Sales Outstanding (DSO) decreased to 76 days in 2018 from 80 days in 2017.

Inventories, net was $16.7 million and $13.7 million at December 28, 2018 and December 29, 2017, respectively. Days' Inventory on Hand (DOH) was 139 days in 2018 and 169 days in 2017 for finished goods, including consignment inventory. The decrease in DOH is due to increased sales of ICL products resulting in more frequent inventory turnover and due to decreased preloaded IOL inventory.

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. As a result of the August 8, 2018 offering, the amount available for any future public offering and sale of equity, debt securities or any combination, is approximately $127 million. 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.

Lines 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 28, 2018) plus a 0.50% spread, and may be renewed quarterly (the current line expires on February 21, 2019). The credit facility is not collateralized. We had 417,500,000 Yen and 500,000,000 Yen outstanding on the line of credit as of December 28, 2018 and December 29, 2017, respectively, (approximately $3.8 million and $4.4 million based on the foreign exchange rates on December 28, 2018 and December 29, 2017, 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 28, 2018, there was 82,500,000 Yen (approximately $747,000 based on the foreign exchange rate on December 28, 2018) available for borrowing and as of December 29, 2017 there were no available borrowings under the line. At maturity on February 21, 2019, this line of credit is intended to be renewed until May 21, 2019, 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 28, 2018 and December 29, 2017), 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 28, 2018 and December 29, 2017.

Covenant Compliance

We are in compliance with the covenants of our credit facilities and lines of credit as of December 28, 2018.

Lease Line of Credit (Capital Leases)

On March 8, 2018, we entered into lease schedule 011 with Farnam Street Financial, Inc. ("Farnam"). The line of credit provides for borrowings of up to $500,000 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. As of December 28, 2018, approximately $387,000 of the line was available for borrowing.

On March 8, 2018, we entered into lease schedule 010R with Farnam. Under 010R, equipment with a cost of $1,560,000 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 28, 2018, approximately $864,000 was outstanding on this capital lease.

On January 31, 2017, we 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 we can opt to continue to rent the equipment, return the equipment, or exercise a fair market value purchase option. As of December 28, 2018 and December 29, 2017, approximately $83,000 and $1,067,000, respectively, was outstanding on this capital lease.

Contractual Obligations

The following table represents the Company's known contractual obligations as of December 28, 2018 (in thousands):

	Payments Due by Period				
Contractual Obligations	Total	1 Year	2 – 3 Years	4 – 5 Years	More than 5 Years
Line of credit (Note 8)*	$3,780	$3,780	$—	$—	$ —
Capital lease obligations (Notes 8 and 12)	1,632	1,153	475	4	—
Operating lease obligations (Note 12)*	6,509	2,606	3,182	709	12
Pension benefit payments (Note 10)*	3,247	97	286	436	2,428
Severance (Note 12)*	41	41	—	—	—
Asset retirement obligation (Note 8)*	206	206	—	—	—
Open purchase orders (Note 12)*	4,668	4,668	—	—	—
Total	$20,083	$12,551	$3,943	$1,149	$ 2,440

*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

We recognize revenue when our contractual performance obligations with customers are satisfied. Our performance obligations are generally limited to single sales orders with product shipping to the customer within a month of receipt of the sales order. Substantially all of our revenues are recognized at a point-in-time when control of our products transfers to the

customer, which is typically upon shipment (as discussed below). We present sales tax and similar taxes we collect from our customers on a net basis (excluded from revenues).

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 combined with an acrylic IOL by the supplier into finished goods inventory (a preloaded acrylic IOL). These finished goods are then sold back to us at an agreed upon, contractual price. We make a profit margin on either type of sale with the supplier and each type of sale is made under separate purchase and sales orders between the two parties resulting in cash settlement for the orders sold or repurchased. For parts that are sold as a final sale, we recognize a sale and those sales are classified as other product sales in total net sales. For the injector parts that are sold to be combined with an acrylic IOL into finished goods, we record 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 we recognize revenues.

For all sales, we are considered the principal in the transaction as we are the party providing specified goods under our control prior to when control is transferred to the customer. Cost of sales includes cost of production, freight and distribution, and inventory provisions, net of any purchase discounts. Shipping and handling activities that occur after the customer obtains control of the goods are recognized as fulfillment costs.

Non-consignment sales

We recognize revenue from non-consignment product sales at a point-in-time when control 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 generally do not have significant deferred as delivery to the customer is generally made within the same or the next day of shipment.

We also enter into certain strategic cooperation agreements with customers in which, as consideration for certain commitments made by the customer, including minimum purchase commitments, we agree, among other things, to pay for marketing, educational training and general support of our products. The provisions in these arrangements allow for these payments to be made directly to the customer or payments can be made directly to a third party for distinct marketing, educational training and general support services provided to or on behalf of the customer by the third party. For payments we make to another party, or reimburse the customer for distinct marketing and support services, we recognize these payments as sales and marketing expense as incurred. These strategic cooperation agreements are generally for periods of 12 months or more with quarterly minimum purchase commitments. We recognize sales and marketing expenses in the period in which it expects the customer will achieve its minimum purchase commitment, generally quarterly, and any unpaid amounts are recorded in Other Current Liabilities in "Other" on the Consolidated Balance Sheets, see Note 7. Reimbursements made directly to the customer for general marketing incentives are treated as a reduction in revenues. Our performance obligations generally occur in the same quarter as the shipment of product.

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

Consignment Sales

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 and recognize revenue for consignment inventory at a point-in-time when we are notified that the lenses have been implanted, thus completing the performance obligation.

Sales Return Reserves

Generally, we may permit returns of product if the product, upon issuance of a Returned Goods Authorization, 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.

Allowance for Doubtful Accounts

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 then 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 - Pension

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."

STAAR Japan has a noncontributory defined benefit pension plan (the "Japan Plan") substantially covering employees of our Japan subsidiary. The Japan Plan has also adopted the recognition and disclosure requirements of ASC 715. 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.

We recognize 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 28, 2018, we had $3.8 million of foreign debt. Our $3.8 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 $38,000.

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. 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 28, 2018, that our disclosure controls and procedures were effective. For purposes of this statement, the term "disclosure controls and procedures" means controls and other procedures of the Company that are designed to ensure that information required to be disclosed by the Company in the reports that it files or submits under the Securities Exchange Act (15 U.S.C. 78a et seq) is recorded, processed, summarized, and reported, within the time periods specified in the Commission's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by the issuer in the reports that it files or submits under the Act is accumulated and communicated to the issuer's management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

Changes in Internal Control over Financial Reporting

There was no change during the fiscal quarter ended December 28, 2018 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 28, 2018, 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 28, 2018.

Report of Independent Registered Public Accounting Firm

Shareholders and Board of Directors

STAAR Surgical Company

Monrovia, California

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 28, 2018, 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 28, 2018, 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 28, 2018 and December 29, 2017, the related consolidated statements of operations, comprehensive income (loss), stockholders' equity, and cash flows for each of the three years in the period ended December 28, 2018, and the related notes and schedule and our report dated February 21, 2019 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 21, 2019

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 “Election of Directors” contained in the proxy statement for the 2019 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 28, 2018.

ITEM 11. Executive Compensation
The information required by this item is incorporated herein by reference to the section entitled “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 “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 “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 “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:

(2) Schedules required by Regulation S-X are filed as an exhibit to this report

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

(3) Exhibits

3.1	Amended and 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 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.(7)
†10.6	Employment Agreement, dated December 16, 2004 by and between the Company and Hans Blickensdoerfer.(8)
10.7	Credit Agreement between STAAR Japan Inc. and Mizuho Bank Inc., dated October 31, 2007.(9)
10.8	Amended Credit Agreement between STAAR Japan Inc. and Mizuho Bank Ltd., dated June 30, 2009.(9)
10.9	Amended Credit Agreement between STAAR Japan Inc. and Mizuho Bank Ltd., dated December 28, 2012.(10)
10.10	Basic Agreement on Unsterilized Intraocular Lens Sales Transactions between Canon Staar Co., Inc. and Nidek Co., Ltd., dated May 23, 2005.(11)
10.11	Basic Agreement on Injector Product Sales Transactions between Canon Staar Co., Inc. and Nidek Co., Ltd., dated May 23, 2005.(11)
10.12	Memorandum of Understanding Concerning Basic Agreements for Purchase and Sale between STAAR Japan Inc. and Nidek Co., Ltd., dated

		December 25, 2008.(11)
10.13		Acrylic Preset Supply Warranty Agreement between STAAR Japan Inc. and Nidek Co., Ltd., dated December 25, 2008.(11)
10.14		Framework Agreement for Loans between Credit Suisse and STAAR Surgical AG, dated September 2013.(12)
†10.15		Form of Executive Severance Agreement.(13)
†10.16		Form of Executive Change in Control Agreement.(13)
10.17		Standard Industrial/Commercial Single – Tenant Lease – Net dated August 17, 2012, by and between the Company and Pacific Equity Partners, LLC.(14)
†10.18		Letter of the Company dated March 27, 2012 to Samuel Gesten, Vice President and General Counsel, regarding compensation.(10)
†10.19		Letter of the Company dated July 27, 2015 to Keith Holliday, Vice President of Research and Development, regarding compensation.(15)
10.20		Amendment Agreement between STAAR Surgical Company and

	Nidek Co., Ltd., dated March 31, 2016.(16)
†10.21	Employment Agreement effective March 1, 2015 by and between the Company and Caren Mason, dated March 1, 2015.(17)
10.22	Form of Option Grant and Stock Option Agreement for employees.(18)
10.23	Form of Option Grant and Stock Option Agreement for Non-Employee Directors.(18)
10.24	Form of Restricted Stock Unit Grant and Agreement.(18)
10.25	Form of Restricted Stock Award Grant and Restricted Stock Award Agreement.(18)

10.26	Form of Amendment to Credit Agreement between STAAR Japan Inc. and Mizuho Bank Ltd.(12)
10.27	Master Lease Agreement dated May 30, 2006 by and between the Company and Farnam Street Financial, Inc.(18)
10.28	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.(18)
10.29	Lease Schedule No. 010R dated March 8, 2018, of Lease Agreement dated May 30, 2006, by and between the Company and Farnam Street Financial, Inc.*
10.30	Lease Schedule No. 011 and Purchase Option dated March 8, 2018 of Lease Agreement dated May 30, 2006, by and between the Company and Farnam Street Financial, Inc.*
10.31	Letter of the Company dated September 27, 2017 to Deborah Andrews, Vice

	President of Finance, Chief Financial Officer, regarding compensation.(19)
10.32	Lease dated August 10, 2017 by and between the Company and 2000 Gold L.P.(20)
10.33	Lease Agreement dated March 1, 2007, between STAAR Surgical AG and Calderari and Schwab AG/SA.(12)
10.34	Lease Agreement commencing May 1, 2018 between Bukewihge Properties, LLC and STAAR Surgical Company.(21)
10.35	Form of Distributorship Agreement.(7)
14.1	Code of Business Conduct and Ethics.(22)
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 28, 2018 formatted in Extensible Business Reporting Language (XBRL): (i) the Consolidated Balance Sheets, (ii) the Consolidated Statements of Operations, (iii) the Consolidated Statements of Comprehensive Income (Loss), (iv) the Consolidated Statements of Stockholders' Equity, (v) the Consolidated Statements of Cash Flows, and (vi) related notes.

* Filed herewith.

** Furnished herewith.

† Management contract or compensatory plan.

(1) Incorporated by reference to Appendix 2 of the Company's Proxy Statement on Form DEF 14A as filed with the Commission on April 13, 2018.

(2) Incorporated by reference to Appendix 3 of the Company's Proxy Statement on Form DEF 14A as filed with the Commission on April 13, 2018.

(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 April 13, 2018.

(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 from the Company's Quarterly Report on Form 10-Q, for the period ended June 29, 2018, as filed with the Commission on August 1, 2018.

(8) Incorporated by reference to the Company's Current Report on Form 8-K as filed with the Commission on October 1, 2009.

(9) 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.
(10) 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.
(11) 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.
(12) Incorporated by reference to the Company's Annual Report on Form 10-K, for the year ended December 29, 2017, as filed with the commission on February 28, 2018.
(13) 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.
(14) Incorporated by reference to the Company's Current Report on Form 8-K

as filed with the Commission on August 23, 2012.

(15) 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.

(16) 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.

(17) Incorporated by reference to the Company's Current Report on Form 8-K as filed with the Commission on March 3, 2015.

(18) 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.

(19) Incorporated by reference to the Company's Current Report on Form 8-K as filed with the Commission on September 28, 2017.

(20) 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.

(21) Incorporated by reference to the Company's Quarterly Report on Form 10-Q, for the period ended March 30, 2018, as filed with the Commission on May 2, 2018.

(22) 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 21, 2019 By: /s/ CAREN MASON
Caren Mason
President and Chief Executive Officer
(principal executive officer)

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

Name	Title	Date
/s/ CAREN MASON Caren Mason	President, Chief Executive Officer and Director (principal executive officer)	February 21, 2019
/s/ DEBORAH J. ANDREWS Deborah J. Andrews	Vice President, Chief Financial Officer (principal accounting and financial officer)	February 21, 2019
/s/ LOUIS E. SILVERMAN Louis E. Silverman	Chairman of the Board, Director	February 21, 2019
/s/ STEPHEN C. FARRELL Stephen C. Farrell	Director	February 21, 2019
/s/ JOHN C. MOORE John C. Moore	Director	February 21, 2019
/s/ WILLIAM P. WALL William P. Wall	Director	February 21, 2019

STAAR SURGICAL COMPANY AND SUBSIDIARIES

CONSOLIDATED FINANCIAL STATEMENTS

Years Ended December 28, 2018, December 29, 2017 and December 30, 2016

TABLE OF CONTENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Shareholders and Board of Directors

STAAR Surgical Company

Monrovia, California

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 28, 2018 and December 29, 2017, the related consolidated statements of operations, comprehensive income (loss), stockholders' equity, and cash flows for each of the three years in the period ended December 28, 2018, 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 28, 2018 and December 29, 2017, and the results of their operations and their cash flows for each of the three years in the period ended December 28, 2018, 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 28, 2018, 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 21, 2019 expressed an unqualified opinion thereon.

Change in Accounting Method Related to Revenue

As discussed in Note 1 to the consolidated financial statements, the Company has changed its method of accounting for revenue during the year ended December 28, 2018 due to the adoption of the Accounting Standards Codification 606, "Revenue from Contracts with Customers."

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 21, 2019

STAAR SURGICAL COMPANY AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

December 28, 2018 and December 29, 2017

(In thousands, except par value amounts)

	2018	2017
ASSETS		
Current assets:		
Cash and cash equivalents	$103,877	$18,520
Accounts receivable trade, net	25,946	17,853
Inventories, net	16,704	13,310
Prepayments, deposits and other current assets	5,045	4,207
Total current assets	151,572	53,890
Property, plant and equipment, net	11,451	9,776
Intangible assets, net	243	271
Goodwill	1,786	1,786
Deferred income taxes	1,278	1,242
Other assets	1,009	967
Total assets	$167,339	$67,932
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Line of credit	$3,780	$4,438
Accounts payable	6,524	6,033
Obligations under capital leases	1,098	1,278
Allowance for sales returns	2,895	—
Other current liabilities	13,431	7,339
Total current liabilities	27,728	19,088