STAAR SURGICAL CO
Form 10-K
March 02, 2017

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K

(Mark One)

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

For the fiscal year ended December 30, 2016
or

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

For the Transition period from to

Commission file number: 0-11634

STAAR SURGICAL COMPANY

(Exact name of registrant as specified in its charter)

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

1911 Walker Avenue

Monrovia, California 91016

(Address of principal executive offices)

(626) 303-7902

(Registrant's telephone number, including area code)

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

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

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

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

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

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

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting

company" in Rule 12b-2 of the Exchange Act. (Check one):

¨ Large accelerated filer þ Accelerated filer ¨ Non-accelerated filer ¨ Smaller reporting company
(Do not check if a smaller reporting company)

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

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

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

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement relating to its 2017 annual meeting of stockholders, which will be filed with the Securities and Exchange Commission pursuant to Regulation 14A within 120 days of the close of the registrant's last fiscal year, are incorporated by reference into Part III of this report.

STAAR SURGICAL COMPANY

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PART I

This Annual Report on Form 10-K contains statements that constitute "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, and the Private Securities Litigation Reform Act of 1995, and is subject to the safe harbor created therein. These statements include comments regarding the intent, belief or current expectations of the Company and its management. Readers can recognize forward-looking statements by the use of words like "anticipate," "estimate," "expect," "intend," "plan," "believe," "will," "forecast" and similar expressions in connection with any discussion of future operating financial performance. STAAR Surgical Company cautions investors and prospective investors that any such forward-looking statements are not guarantees of future performance and involve risks and uncertainties, and that actual results may differ materially from those projected in the forward-looking statements. We caution you not to place undue reliance on these forward-looking statements and to note they speak only as of the date hereof. Factors that could cause actual results to differ materially from those set forth in the forward-looking statements are included in the risk factors set forth in Item 1A, "Risk Factors." We disclaim any intention or obligation to update or revise any financial projections or forward-looking statements due to new information or other events.

Item 1. Business

STAAR Surgical Company designs, develops, manufactures, and sells implantable lenses for the eye and delivery systems used to deliver the lenses into the eye. We are the leading manufacturer of lenses used worldwide in corrective or "refractive" surgery. Our goal is to position our refractive lenses throughout the world as primary and premium solutions for patients seeking visual freedom from wearing glasses or contact lenses while achieving excellent visual acuity through refractive vision correction. We also make lenses for use in surgery that treats cataracts.

Originally incorporated in California in 1982, STAAR Surgical Company reincorporated in Delaware in 1986. Unless the context indicates otherwise, "we," "us," the "Company," and "STAAR" refer to STAAR Surgical Company and its consolidated subsidiaries.

A glossary explaining many of the technical terms used in this report begins on page 12. The reader may also find it helpful to refer to the discussion of the structure and function of the human eye that begins on page 12.

Operations

STAAR has significant operations globally. Activities outside the United States ("U.S.") accounted for 88% of our total sales in fiscal year 2016, primarily due to the pacing of product approvals and commercialization that tend to occur first outside the United States. STAAR sells its products in more than 60 countries, with direct distribution in Japan, the U.S., Spain, Germany, Canada, and the U.K., and independent distribution in the remainder of the world.

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

- *United States.* STAAR operates its global administrative headquarters and principal manufacturing facility in Monrovia, California. The Monrovia manufacturing facility primarily makes the Visian implantable Collamer lens product family, including the EVO Visian ICL (collectively referred to as ICLs), Collamer intraocular lenses (IOLs), preloaded silicone IOLs, and injector systems. We manufacture the raw material for Collamer lenses (both IOLs and ICLs) and the AquaFLOW Device (for the treatment of glaucoma) in our facility in Aliso Viejo, California.

- *Switzerland*. STAAR operates an administrative and distribution facility in Nidau, Switzerland under its wholly owned subsidiary, STAAR Surgical AG. The Nidau facility also maintains manufacturing capabilities for STAAR's ICL products and the AquaFLOW Device.

- *Japan*. STAAR operates administrative and distribution facilities in Japan under its wholly owned subsidiary, STAAR Japan Inc. STAAR Japan's administrative facility is in Shin-Urayasu and its distribution facility is in Ichikawa City. STAAR performs final packaging of its silicone preloaded IOL injectors and final inspection of its acrylic preloaded IOL injectors at the Ichikawa City facility.

Financial Information about Segments and Geographic Areas

100% of the Company's sales are generated from the ophthalmic surgical product segment and, therefore, the Company operates as one operating segment for financial reporting purposes. The Company's principal products are ICLs used in refractive surgery and IOLs used in cataract surgery. See Note 16 to the Consolidated Financial Statements for financial information about product lines and operations in geographic areas.

Principal Products

In designing our products, we seek to delight patients and surgeons by:

- Improving patient outcomes;
- Minimizing patient risk; and
- Simplifying ophthalmic procedures or post-operative care for the surgeon and the patient.

EVO Visian ICL and Visian ICL. Refractive surgery corrects visual disorders that glasses or contact lenses have traditionally treated (myopia, hyperopia, astigmatism, and presbyopia). The field of refractive surgery includes both lens-based procedures, using products like our ICL, and laser-based procedures like LASIK. The ICL product line treats a wide range of refractive errors within commonly known vision disorders such as myopia (nearsightedness), hyperopia (farsightedness) and astigmatism.

The ICL folds for minimally invasive implantation behind the iris and in front of the natural crystalline lens, using techniques similar to those used to implant an IOL during cataract surgery, except that the natural lens remains intact in the eye. Lenses of this type are generically called “phakic IOLs” or “phakic implants” because they work along with the patient’s natural lens, or *phakos*, rather than replacing it. The surgeon typically implants the ICL using topical anesthesia on an outpatient basis. The patient usually experiences immediate vision improvement within a day.

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

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

size intended to optimize the flow of fluid within the eye without affecting the quality of vision. The central port also eliminates the need for the surgeon to perform a YAG peripheral iridotomy procedure days before the ICL implant. The CentraFLOW technology makes the visual outcomes of the ICL available through a simpler and more comfortable surgical implantation experience. We are authorized to sell the TICL and the ICL with CentraFLOW technology in the following ex-U.S. regions: the 31 countries that require the European Union CE Mark, China, Canada, Korea, Japan, India, Argentina, Singapore, and several countries in the Middle East. STAAR submitted its application for U.S. approval of the TICL to the FDA in 2006, and our application remains under review (see "Regulatory Matters – Regulatory Requirements in the United States"). In December 2015, we received the CE Mark for EVO+, an ICL with CentraFLOW technology and an expanded optical zone of up to 20%. We believe the expanded optical zone may further improve certain patients' visual experience, thus making the ICL increasingly desirable for both patients and ophthalmic surgeons. We are authorized to sell the EVO+ in the following ex-U.S. regions: the 31 countries that require the European Union CE Mark, Korea, Japan, Hong Kong, Turkey, and several countries in the Middle East. The Hyperopic ICL, which treats far-sightedness, is sold primarily in countries that require the European Union CE Mark. Typically, the refractive surgery where an ICL is implanted is an elective procedure paid for or financed by the patient.

Globally, the ICL is available for myopia and hyperopia and is available in multiple models, powers and lengths totaling hundreds of different types of inventoried lenses. This requires us to carry a significant amount of inventory to meet customer preference for rapid delivery. Outside the U.S., the TICL is available for myopia in the same powers and lengths and carries additional parameters of cylinder and axis. In 2016, approximately 80% of TICL orders were available for shipment in less than one week from receipt. The remaining approximately 20% of TICL orders were custom-made.

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

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

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

Minimally Invasive Intraocular Lenses (IOLs). We produce and market a line of foldable IOLs for use in minimally invasive cataract surgical procedures. Because these lenses fold, surgeons can implant them into the eye through a small incision less than 3mm in length. Surgeons prefer foldable lenses and small incisions because clinical evidence has shown that larger incisions can induce corneal astigmatism, extend healing times, and increase the possibility of infection. Once inserted, the IOL unfolds naturally to replace the cataractous lens.

In most of the countries where STAAR does business, government agencies reimburse most or all of the cost of cataract surgery and IOLs.

Currently, our foldable IOLs are manufactured from both our proprietary Collamer material and silicone. STAAR offers both materials in two differently configured styles: the single-piece design where both the optic and haptics are made of the same material and the three-piece design where Polyimide loop haptics are attached to the optic. We believe that the physical and optical properties of Collamer, which has a high-water content, give it distinct advantages as a material for prosthetic IOLs used in cataract surgery. The selection of one style over the other is primarily based on the preference of the ophthalmologist. STAAR also sells aspheric IOLs made of silicone and Collamer that use optical designs that produce a clearer image than traditional spherical lenses, especially in low light. For example, the STAAR nanoFLEX IOL is a single piece Collamer aspheric optic that can be delivered through a micro-incision using STAAR’s nanoPOINT Injection System.

Also, in Japan and parts of Europe, we sell a “Preloaded Injector” with a silicone or acrylic IOL packaged and shipped in a pre-sterilized, disposable injector ready for use in cataract surgery. We believe the Preloaded Injector offers surgeons improved convenience and reliability. The acrylic lens-based Preloaded Injector uses a lens supplied by a third party. The supplier also assembles and sells the acrylic Preloaded Injector under its own brand, using injector parts purchased from us.

Sales of IOLs accounted for approximately 24% of our total sales in fiscal 2016, 26% of our total sales in fiscal 2015, and 33% of our total sales in fiscal 2014.

Other Surgical Products

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

Sources and Availability of Raw Materials

STAAR uses a wide range of raw materials in the production of its products. STAAR purchases most of the raw materials and components from external suppliers. Some of our raw materials are single-sourced due to regulatory constraints, cost effectiveness, availability, quality, and vendor reliability issues. Many of our components are standard parts or materials and are available from a variety of sources. We do not typically pursue regulatory and quality certification of multiple sources of supply.

Patents, Trademarks, and Licenses

We strive to protect our investment in the research, development, manufacturing, and marketing of our products through the use of patents, trademarks, licenses, trade secrets, and copyrights. We own or have rights to a number of patents, licenses, trademarks, copyrights, trade secrets, know-how and other intellectual property directly related and important to our business. As of December 30, 2016, we owned 67 United States and foreign patents and had 20 patent applications pending. We believe that no particular patent is so important that its loss or expiration would materially adversely affect our operations as a whole.

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

Worldwide, we sell all our major products under trademarks we consider to be important to our business. STAAR®, EVO Visian ICL™, Evolution in Visual Freedom™, Visian®, Collamer®, CentraFLOW®, AquaPORT®, nanoFLEX® nanoPOINT™, Afinity™, and AquaFLOW™ are trademarks or registered trademarks of STAAR in the U.S. and other countries. The scope and duration of trademark protection varies widely throughout the world. In some countries, trademark protection continues only as long as the mark is used. Other countries require registration of trademarks and the payment of registration fees. Trademark registrations are generally for fixed but renewable terms.

We protect our proprietary technology, in part, through confidentiality and nondisclosure agreements with employees, consultants, and other parties. Our confidentiality agreements with employees and consultants generally contain standard provisions requiring those individuals to assign to STAAR, without additional consideration, inventions conceived or reduced to practice by them while employed or retained by STAAR, subject to customary exceptions. We cannot provide any assurance that employees and consultants will abide by the confidentiality or other terms of their agreements. Despite measures taken to protect our intellectual property, unauthorized parties may copy aspects of our products or obtain and use information that we regard as proprietary.

Seasonality

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

Working Capital Requirements

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

Distribution and Customers

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

We sell our products directly through our own sales representatives in Japan, the U.S., Spain, Germany, Canada, and the U.K., and, supplemented by independent distributors, in approximately 60 additional countries worldwide. We maintain a global marketing team, as well as regional marketing personnel to support the promotion and sale of our products. The global marketing department supports selling efforts by developing and providing promotional materials, speakers' programs, digital and social media sites, participation in trade shows and technical presentations. Where we distribute products directly, we rely on local sales representatives to help generate sales by promoting and demonstrating our products with physicians. In the U.S., we also rely on independent sales representatives to sell our products under the supervision of directly employed sales managers. Our clinical affairs personnel provide training and educational courses globally.

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

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

Net Sales to Shanghai Langsheng			
Fiscal Year	Net Sales ($, in thousands)	Net Sales as Percentage of Consolidated Net Sales	
2016	$ 16,025	19.4	%
2015	$ 11,851	15.4	%
2014	$ 7,990	10.7	%

Backlog

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

Government Contracts

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

Competition

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

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In the refractive market, our ICL technology competes with other elective surgical procedures such as laser vision correction (e.g. LASIK) for those consumers who are looking for an alternative to eyeglasses or contact lenses to correct their vision. In the cataract surgery market, our IOLs primarily compete based on our technology's quality and value.

We believe our primary competition in selling the ICL to patients seeking surgery to correct refractive conditions lies not in similar products to the ICL, but in laser surgical procedures. Novartis (formerly Alcon), Johnson & Johnson (formerly Advanced Medical Optics or AMO), Valeant (formerly Bausch & Lomb or B&L), and Carl Zeiss Meditec AG, all market lasers for corneal refractive surgery and promote their sales worldwide.

Phakic implants that compete with the ICL are also available in the marketplace. The three principal types of phakic IOLs (PIOLs) are (1) posterior chamber designs like the ICL, (2) iris clip anterior chamber PIOLs like the Artisan® and Artiflex® lenses made by Ophtec (Artisan® has been distributed by AMO under the Verisyse® brand), and (3) angle-supported anterior chamber PIOLs like the Cachet® made by Novartis (formerly Alcon) which has been sold outside the U.S. We believe the ICL has compelling clinical advantages over the other lenses, which are reflected in our strong market share of the global phakic IOL market. The ICL is the only foldable, minimally invasive PIOL approved for sale in the U.S. Competitors from Asia are beginning to appear in the market with their low-cost version of an implantable contact lens, increasing the level of competition.

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

The Human Eye

The following discussion provides background information on the structure, function, and some of the disorders of the human eye to enhance the reader's understanding of our products described in this report. The human eye is a specialized sensory organ capable of receiving visual images and transmitting them to the visual center in the brain. The eye has an anterior segment and a posterior segment that are separated by the natural crystalline lens.

The anterior segment consists of the cornea, the iris and ciliary body and the trabecular meshwork. It is filled with a water-based fluid called aqueous humor and is divided, by the iris, into an anterior chamber and a posterior chamber. The cornea is a clear lens at the front of the eye through which light first passes and is focused towards the back of the eye. The interior surface of the cornea is lined with a single layer of flat, tile-like endothelial cells, whose function is to maintain the transparency of the cornea. The iris is a pigmented muscular curtain located behind the cornea which

opens and closes to regulate the amount of light entering the eye through the pupil, an opening at the center of the iris. The crystalline lens is located behind the iris that completes the focusing of light and can change shape to focus objects at different distances onto the retina, located in the back of the eye. The trabecular meshwork, a drainage channel located between the iris and the surrounding white portion of the eye, maintains a normal pressure in the anterior chamber of the eye by draining excess aqueous humor.

The posterior segment of the eye that is behind the natural lens is filled with a jelly-like material called the vitreous humor. The retina is a layer of nerve tissue in the back of the eye consisting of millions of light receptors called rods and cones, which receive the light image and transmit it to the brain via the optic nerve.

Common visual disorders, disease or trauma can affect the eye. One of the most prevalent ocular disorders is cataracts. Cataract formation is generally an age-related disorder that involves the hardening and loss of transparency of the natural crystalline lens, impairing visual acuity.

Refractive disorders, which generally are not age-related, include myopia, hyperopia, and astigmatism. A normal, well-functioning eye receives images of objects at varying distances from the eye and focuses the images on the retina. Refractive errors occur when the eye’s natural optical system does not properly focus an image on the retina. Myopia, also known as nearsightedness, occurs when the eye’s lens focuses images in front of the retina. Hyperopia, or farsightedness, occurs when the eye’s lens focuses images behind the plane of the retina. Individuals with myopia or hyperopia may also have astigmatism. Astigmatism is due to an irregular curvature of the cornea or defects in the natural lens. In an eye with astigmatism, light fails to come to a single focus on the retina. Instead, two or more focus points occur that results in blurred vision. Presbyopia is an age-related refractive disorder that limits a person’s ability to see in the near and middle distance range as the natural crystalline lens loses its elasticity, reducing the eye’s ability to accommodate or adjust its focus for varying distances.

Regulatory Matters

Nearly all countries where we sell our products have regulations requiring premarket clearance or approval of medical devices by governmental or regulatory authorities. Various federal, state, local and foreign laws also apply to our operations, including, among other things, working conditions, laboratory, clinical, advertising and promotions, and design and manufacturing practices, and the use and disposal of hazardous or potentially hazardous substances.

The requirements for clearance or approval to market medical products vary widely by country. The requirements range from minimal requirements to rigorous requirements comparable to those established by the U.S. Food and Drug Administration (FDA). Obtaining clearance or approval to distribute medical products is complex, costly, and time-consuming in virtually all the major markets where we sell medical devices. We cannot give any assurance that any new medical devices we develop will be cleared or approved in any country where we propose to sell our medical devices or, if approved, whether such approvals will be granted in a timely or cost-effective manner, be as broad in scope as we seek, or be conditioned on post-market study requirements or restrictive labeling. We also cannot give any assurance that if our medical devices are approved for sale in a country, subsequent action will not be taken by the responsible regulatory authorities in the country with respect to our medical devices that might affect our ability to maintain the required approvals in the country or to continue to sell our medical devices in the country. The regulatory requirements in our most important current markets, the U.S., Europe, Japan, China, and Korea are discussed below.

Regulatory Requirements in the United States.

Under the federal Food, Drug & Cosmetic Act, as amended (the Act), the FDA has the authority to regulate, among other things, the design, development, manufacturing, preclinical and clinical testing, labeling, product safety, marketing, sales, distribution, premarket clearance and approval, recordkeeping, reporting, advertising, promotion, post-market surveillance, and import and export of medical devices.

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

Each medical device we seek to commercially distribute in the United States must first receive clearance to market under a notification submitted pursuant to Section 510(k) of the Act, known as the 510(k) premarket notification, or premarket approval (PMA) from the FDA, unless specifically exempted by the agency or subject to another form of FDA premarket review. The FDA classifies all medical devices into one of three classes. The FDA establishes procedures for compliance based upon the device's classification as Class I (general controls, such as establishment registration and device listing with FDA, labeling and record-keeping requirements), Class II (performance standards in addition to general controls) or Class III (premarket approval (PMA) required before commercial marketing). Devices deemed to pose lower risk are categorized as either Class I (low risk) or II (moderate risk). Manufacturers of Class II devices are generally required to submit to the FDA a 510(k) premarket notification requesting clearance of the device for commercial distribution in the United States. Most low risk (Class I) devices and some Class II devices are exempt from this requirement. The FDA deems Class III devices to pose the greatest risk and are the most extensively regulated. These devices include life-supporting, life sustaining, or implantable devices, or devices deemed not substantially equivalent to a previously 510(k) cleared device. The effect of assigning a device to Class III is to require each manufacturer to submit to the FDA a PMA that includes information on the safety and effectiveness of the device. The FDA reviews device applications and notifications through its Office of Device Evaluation (ODE).

510(k) Clearance. Our lens injector systems are Class I devices subject to the 510(k) premarket review and clearance process. A medical device that is substantially equivalent to either a previously-cleared medical device or a device that was in commercial distribution before May 28, 1976 for which the FDA has not yet called for the submission of a PMA, or is a device that has been reclassified from Class III to either Class II or I may be eligible for the FDA's 510(k) premarket notification process. FDA clearance under Section 510(k) of the Act does not imply that the safety, reliability, and effectiveness of the medical device has been approved or validated by the FDA. The review period and FDA determination as to substantial equivalence generally takes from three to twelve months from the date the application is submitted and filed. However, the process may take significantly longer, and clearance is never assured. Although many 510(k) premarket notifications are cleared without clinical data, in some cases, the FDA requires significant clinical data to support substantial equivalence. In reviewing a premarket notification, the FDA may request additional information including clinical data, which may significantly prolong the review process.

After a device receives 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, will require a new 510(k) clearance or could require premarket approval. The FDA requires each manufacturer to make its own initial determination as to whether a change meets this threshold. However, the FDA can review any such decision and can disagree with a manufacturer's determination. If the FDA disagrees with a manufacturer's determination, the FDA can require the manufacturer to cease marketing or recall the modified device until 510(k) clearance or a PMA is obtained.

Premarket Approval. Our IOLs, ICLs, and AquaFLOW Devices are Class III devices subject to the PMA approval process. When 510(k) clearance is not available, the more rigorous PMA process requires us to demonstrate independently that the new medical device is safe and effective for its intended use. A PMA must be supported by, among other things, extensive technical, pre-clinical, clinical testing, manufacturing, and labeling data to demonstrate to the FDA's satisfaction the safety and effectiveness of the device.

After a PMA application is submitted and filed, the FDA begins an in-depth review of the submitted information, which typically takes between one and three years, but may take significantly longer. During the review period, the FDA may request additional information or clarification of information already provided. In addition to its own review, the FDA may organize an independent advisory panel of experts to review the PMA whenever a device is the first of its kind or the FDA otherwise determines panel review is warranted. The FDA holds panels on a regular basis, but the need to schedule panel review usually adds some weeks or months to the review process. In addition, the FDA will conduct a pre-approval inspection of the manufacturing facility to ensure compliance with Quality System Regulation (QSR) which imposes elaborate design development, testing, control, validation, documentation, complaint handling, supplier control, and other quality assurance procedures in the design and manufacturing process. The FDA may approve a PMA application with post-approval conditions intended to ensure the safety and effectiveness of the device including, among other things, restrictions on labeling, promotion, sale and distribution and conduct of additional post-approval clinical studies or collection of long-term follow-up from patients in the clinical study that supported approval. Failure to comply with the conditions of approval can result in materially adverse enforcement action, including the loss or withdrawal of the approval.

If a manufacturer plans to make significant modifications to the manufacturing process, labeling, or design of an approved PMA device, the manufacturer must submit an application called a “PMA Supplement” regarding the change. The FDA generally reviews PMA Supplements on a 180-day agency timetable, which may be extended if significant questions arise in review of the supplement. A manufacturer may implement limited changes prior to the FDA’s review of a PMA Supplement. The FDA designates some PMA Supplements as “panel-track” supplements, which means that the agency believes review by an advisory panel may be warranted. Designation as a panel-track supplement does not necessarily mean that panel review will occur.

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

Oversight of compliance with quality, medical device reporting, clinical study, and other regulations. Both before and after we receive premarket clearance or approval and release a product commercially, we have ongoing responsibilities under FDA regulations. The FDA reviews design and manufacturing practices, labeling and record keeping, product complaints and manufacturer’s required reports of adverse experiences, product corrections and removals, and other information to identify potential problems with marketed medical devices. We are also subject to periodic inspection by the FDA for compliance with the FDA’s Quality System Regulation (QSR) and other requirements, such as requirements for advertising and promotion. The Good Manufacturing Practice (GMP) regulations for medical devices embodied in the QSR govern the methods used in, and the facilities and controls used for, the design, manufacture, packaging, labeling, and servicing of all finished medical devices intended for human use.

The FDA’s Bioresearch Monitoring Program (BIMO), reviews our activities as a sponsor of clinical research. BIMO conducts facilities inspections as part of a program designed to ensure that data and information contained in requests for IDEs, PMA applications and 510(k) submissions are scientifically valid, reliable, and accurate. Another objective of the program is to ensure that human subjects are protected from undue hazard or risk during scientific investigations.

If the FDA were to conclude that we are not in compliance with applicable laws or regulations, or that any of our medical devices are ineffective or pose an unreasonable health risk, the FDA could require us to notify health professionals and others that the devices present unreasonable risk or substantial harm to public health, order a recall, repair, replacement, or refund of the devices, detain, or seize adulterated or misbranded medical devices, or ban the medical devices. The FDA may also issue warning letters or untitled letters, refuse our request for 510(k) clearance or PMA approval, revoke existing 510(k) clearances or PMA approvals previously granted, impose operating restrictions, enjoin, and restrain certain violations of applicable law pertaining to medical devices and assess civil or criminal penalties against our officers, employees, or us. The FDA may also recommend prosecution to the Department of Justice. In the case of devices subject to pending premarket clearance or approval applications, FDA has broad authority to halt the review of applications and require significant additional data analyses, audits, and other corrective actions where clinical data contained in an application are deemed to be actually or potentially unreliable, inaccurate, or not in compliance with clinical study or good clinical practice requirements.

For example, in 2007 we received a warning letter following a BIMO inspection that identified negative inspectional observations. Prior to the inspection and the warning letter, we submitted a PMA supplement for the TICL to the FDA on April 28, 2006, which the agency designated as a panel-track supplement. In August 2007, following negative inspectional observations and the warning letter the FDA Office of Device Evaluation placed an integrity hold on our TICL application. Over a two-year period, we took a number of corrective actions to address BIMO's concerns and to remove the integrity hold, including engaging an independent third party to conduct a 100% audit of patient records in the TICL clinical study, along with an audit of clinical systems to ensure accuracy and completeness of data before resubmitting the application. On July 21, 2009, the FDA notified us that because of our corrective actions the FDA had removed the integrity hold on the application for approval of the TICL, and would resume its consideration of the application. In February 2010 and November 2011, we received letters of deficiency from the FDA outlining additional questions. After several communications with and additional data submissions to the FDA, on March 14, 2014 an FDA Ophthalmic Devices Panel of the Medical Devices Advisory Committee, which assessed our PMA Supplement submission seeking approval of the TICL, voted favorably in response to the three questions posed to it by the FDA's Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices regarding the TICL's safety and effectiveness as well as whether the TICL's benefits outweigh its risks.

On May 27, 2014, we received a warning letter from the FDA (2014 Warning Letter) citing alleged violations of current good manufacturing practice (cGMP) regulations that were identified by the FDA during an inspection of our manufacturing facility in Monrovia, California between February 10, 2014, and March 21, 2014. To summarize, the 2014 Warning Letter observations require remedial action in four general areas: design control documentation; validation of software for an on-line calculator; data collection and trending of ICL vault complaints; and shelf life data on the ICL product. The 2014 Warning Letter provides that, until the Company addresses the deficiencies to the FDA's satisfaction, the FDA will not approve PMAs for the Company's Class III devices where the applications are reasonably related to the cGMP violations cited in the 2014 Warning Letter.

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

Healthcare Fraud and Abuse Laws and Regulations.

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

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

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

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

- the federal physician sunshine requirements under the Patient Protection and Affordable Care Act of 2010, which requires manufacturers of drugs, devices, biologics, and medical supplies to report annually to the Centers for Medicare & Medicaid Services information related to payments and other transfers of value relating to certain drugs, devices, biologics, and medical supplies to physicians, other healthcare providers, and teaching hospitals, and ownership and investment interests held by physicians and other healthcare providers and their immediate family members;

- the federal Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, which governs the conduct of certain electronic healthcare transactions and protects the security and privacy of protected health information; and

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

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

Regulatory Requirements Outside the United States.

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

The method of assessing conformity varies depending on the class of the product, but normally involves a combination of self-assessment by the manufacturer and a third-party assessment by a "Notified Body." Notified Bodies are a group of private quality-monitoring organizations that are accredited to review medical devices and to monitor quality systems and adverse event reporting. The independent Notified Bodies perform, on a privatized basis, functions similar to the FDA in the U.S. and the Pharmaceuticals and Medical Devices Agency (PMDA) in Japan. Our facilities in the United States and Switzerland are subject to regular inspection by a designated Notified Body. Other countries, such as Switzerland, have voluntarily adopted laws and regulations that mirror those of the European Union with respect to medical devices, and a number of countries outside of Europe permit importation of devices bearing the CE Mark.

We have affixed the CE Mark to all our principal products sold in CE Mark jurisdictions including ICLs, IOLs, injector systems and our AquaFLOW Device.

Medical Device Regulation in Japan. The Japanese Ministry of Health, Labor, and Welfare (MHLW) regulates the sale of medical devices under Japan's Pharmaceutical Affairs Law (PAL). The PMDA, a quasi-governmental organization, performs many of the medical device review functions for MHLW. Medical devices generally must undergo thorough safety examinations and demonstrate medical efficacy before the MHLW grants *shonin* (premarket device approval) or *ninsho* (certification). Manufacturers and resellers (referred to as Marketing Authorization Holders or MAHs) must also satisfy certain requirements before the MHLW grants a business license, or *kyoka*. Requirements for manufacturers and MAHs include compliance with Japanese regulations covering GQP (good quality control practice) and GVP (good vigilance practice), which largely include conformity to the ISO 13485 standard and are similar to good manufacturing practice and post-market surveillance requirements in the United States, as well as the assignment of internal supervisors over marketing, quality assurance, and safety control.

Approval for a new medical device that lacks a substantial equivalent in the Japanese market will generally require the submission of clinical trial data. Only a licensed MAH can apply for premarket device approval in Japan, and in most cases, the clinical trial data must include data gathered from Japanese subjects. For example, STAAR Japan conducted a separate clinical trial in Japan for the *shonin* application for the ICL. Also, approval for a new medical device will require the manufacturer to undertake to reexamine the safety and efficacy of the device with a review of post-market data gathered within a certain period - normally four years - after approval. The specific post-market reexamination requirement for a medical device is announced at the time of approval.

STAAR Japan currently holds *shonin* approval for the ICL products, preloaded injectors, and their associated lenses, and *kyoka* licensing as a manufacturer and MAH of medical devices. The sponsor of a clinical trial submitted to the MHLW must strictly follow Good Clinical Practice (GCP) standards, and must follow the trial with standard Good Post-market Study Practice (GPSP) reporting and a follow-up program. MHLW and PMDA also assess the quality management systems of manufacturers and the conformity of products to the requirements of PAL. STAAR is subject to inspection for compliance by these agencies. A company's failure to comply with PAL can result in severe penalties, including revocation or suspension of a company's business license and possible criminal sanctions. If the PMDA were

to conclude that we are not in compliance with applicable laws or regulations, or that any of our medical devices are ineffective or pose an unreasonable health risk, they could take a variety of regulatory or legal actions, similar to the FDA, which could have a material and negative impact on the Company.

Medical Device Regulation in China and Korea. Sales of our products in China and Korea, as in other countries, are also subject to regulatory requirements. In China, medical devices such as our ICLs require testing by a government recognized laboratory qualified as a medical device testing center in accordance with Chinese standards. Results from the testing center, together with registration documents, are submitted to the Center for Medical Device Evaluation (CMDE) of the Chinese FDA (CFDA) for technical evaluation and if accepted, then approval and registration by CFDA. In China, we obtain registration of our products from CFDA ourselves. In Korea, medical devices such as our ICLs and IOLs require registration and approval from the Korean Ministry of Food and Drug Safety (MFDS) prior to commercialization. Typically, the MFDS requires similar documentation as required to obtain a CE Mark. Our distributor in Korea is contractually required to obtain, with our assistance, the necessary health registrations, governmental approvals, or clearances to import, market and sell our products. In Korea, we provide our distributor with information and data to obtain appropriate registrations and approvals, and the distributor in each country obtains such registrations. If the CFDA or MFDS were to conclude that we are not in compliance with applicable laws or regulations, or that any of our medical devices are ineffective or pose an unreasonable health risk, they could take a variety of regulatory or legal actions in their respective countries, similar to the FDA, which could have a material and negative impact on the Company.

Third Party Coverage and Reimbursement.

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

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

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

In international markets, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted cost containment initiatives similar to those in the United States. There can be no assurance that third-party coverage and reimbursement will be available or adequate, or that such policies or any future legislation or regulation will not adversely affect the demand for our IOLs or our ability to sell these products at prices we consider adequate.

Research and Development

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

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

During 2017, we intend to continue our focus on research and development in the following areas:

·Development of presbyopia-correcting ICLs;

- Development of preloaded injector systems for ICLs;

- Development of presbyopia-correcting IOLs; and

- Development of a new generation of ICLs and materials.

Environmental Matters

We are subject to federal, state, local and foreign environmental laws, and regulations. We believe that our operations comply in all material respects with applicable environmental laws and regulations in each country where we do business. We do not expect compliance with these laws to affect materially our capital expenditures, earnings, or competitive position. We have no plans to invest in material capital expenditures for environmental control facilities for the remainder of our current fiscal year or for the next fiscal year. We are not aware of any pending actions, litigation or significant financial obligations arising from current or past environmental practices that are likely to have a material adverse impact on our financial position. However, environmental problems relating to our properties could develop in the future, and such problems could require significant expenditures. In addition, we cannot predict changes in environmental legislation or regulations that may be adopted or enacted in the future and that may adversely affect us.

Employees

As of February 15, 2017, we had approximately 336 full-time equivalent employees.

Code of Ethics

STAAR has adopted a revised Code of Business Conduct and Ethics that applies to all its directors, officers, and employees. The Code of Business Conduct and Ethics is posted on our website, *www.staar.com — Investor Information: Corporate Governance.*

Additional Information

We make available free of charge through our website, *www.staar.com*, our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to any reports filed or furnished pursuant to Section 13(a) of the Securities Exchange Act of 1934, as soon as reasonably practicable, after those reports are filed with or furnished to the Securities and Exchange Commission (“SEC”).

The public may read any of the items we file with the SEC at the SEC's Public Reference Room at 100 F Street, NE, Washington, DC 20549. The public may obtain information about the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC also maintains an Internet site that contains reports, proxy and information statements, and other information regarding STAAR and other issuers that file electronically with the SEC at http://www.sec.gov.

Glossary

The following glossary is intended to help the reader understand some of the terms used in this Report.

acrylic – a broadly used family of plastics. Acrylic materials used in IOLs have been both water repelling (*hydrophobic*) and water-absorbing (*hydrophilic*). The most popular IOLs in the U.S., Europe and Japan are made of a flexible, water-repellent acrylic material.

aspheric – aspheric lenses are lenses that are designed in a shape that creates a more clearly focused image than traditional *spheric* lenses. By reducing *spherical aberrations,* IOLs that feature aspheric optics generally deliver better night vision and contrast sensitivity than spheric IOLs.

collagen copolymer - compounds formed by joining molecules of collagen derived from biological sources with synthetic monomer molecules. STAAR's Collamer® is a collagen copolymer engineered specifically for use in implantable lenses.

contrast sensitivity - the ability to visually distinguish an object from its background.

crystalline lens – the natural lens that is present in the eye at birth, which is a clear structure, located behind the iris that changes shape to focus light onto the retina.

excimer laser – a specialized ultraviolet laser used in ophthalmology to cut or shape eye tissue. The excimer laser is used during LASIK and PRK surgery.

foldable IOL – an intraocular lens made of flexible material, which can be inserted with an injector system through a small incision in minimally invasive cataract surgery.

haptic – the part of an IOL that contacts the structures of the eye and holds the IOL in place. IOLs in which the haptic is also a part of the optic material is called a single-piece IOL, while IOLs in which the haptics are attached to the

optic is called a three-piece IOL.

hyperopia – the refractive disorder commonly known as farsightedness, which occurs when the eye's lens focuses images behind the plane of the retina rather than on the retinal surface. A person with hyperopia cannot see close objects without glasses or contact lenses. Because presbyopia often results in the need for reading glasses, it is sometimes confused with farsightedness.

intraocular – within the eye.

injector or injector system – a device in the form of a syringe that is used to deliver a foldable IOL into the eye through a slender nozzle in minimally invasive cataract surgery.

iridotomy – a small hole created in the iris, usually made with a YAG laser. Prior to implantation of some ICL models a YAG *peripheral* iridotomy is made in an unobtrusive area at the periphery of the iris to ensure continued fluid flow in the eye after implantation. The ICL with CentraFLOW technology, marketed with the brand names EVO and EVO+, have a central port for fluid flow, which eliminates the need for an iridotomy or iridectomy.

LASIK – an acronym for laser-assisted in-situ keratomileusis, a surgical operation that reshapes the cornea to correct nearsightedness, farsightedness, or astigmatism. LASIK involves first the cutting of a hinged flap to separate the surface layer of the cornea, using a microkeratome (a special blade) or a laser. An excimer laser is then used to burn tissue away and reshape the inner cornea, after which the flap is returned to position.

myopia – the refractive disorder also known as nearsightedness, which occurs when the eye's lens focuses images in front of the retina rather than on the retinal surface. A person with myopia cannot clearly see distant objects without glasses or contact lenses.

ophthalmologist – a surgeon who specializes in the diseases and disorders of the eye and the related visual pathway.

ophthalmic – of or related to the eye.

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

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

Preloaded Injector - a silicone or acrylic IOL packaged and shipped in a pre-sterilized, disposable injector. This differs from the conventional method of packaging IOLs, which requires the surgeon or an assistant to manually load each lens into an injector before surgery.

presbyopia – an age-related condition in which the crystalline lens loses its ability to focus on both near and far objects. People who have had normal vision will typically begin to need glasses for reading or other close tasks at some point after age 40 due to presbyopia.

QSR - the FDA's Quality System Regulation, or current Good Manufacturing Practice (cGMP) regulation, includes requirements related to the methods used in, and the facilities and controls used for, designing, manufacturing, packaging, labeling, storing, installing, and servicing of medical devices intended for human use. The regulation sets forth the framework for medical device manufacturers to follow in achieving quality requirements, including requirements related to complaint handling and control of purchased or supplied services, components, and materials bearing on the quality of medical devices.

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

refractive market – as used in this report "refractive market" means the overall market volume for refractive surgical procedures of all kinds, including LASIK, PRK, RLE, the ICL product family and other phakic IOLs. As used in this report, the term does not include sales of non-surgical products like eyeglasses and contact lenses.

silicone – a type of plastic often used in implantable devices that is inert, generally flexible and water-repelling.

single-piece IOL – in a single piece IOL the haptics and the optic are fashioned from a single piece of lens material.

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

three-piece IOL – a three-piece IOL has a central, disk-shaped optic and two spring-like haptics attached at either side. The haptics are positioned against structures of the eye to hold the IOL in place.

toric – refers to the shape of a lens designed to correct astigmatism, which has greater refractive power in some sections of the lens than others.

YAG – an acronym for yttrium-aluminum-garnet, a mineral crystal. Lasers using neodymium-doped yttrium aluminium garnet crystals (Nd:YAG) generate a high-energy beam that can be used in a number of ophthalmic procedures, including creating iridotomies before implantation of some models of the ICL.

Item 1A. Risk Factors

Our short and long-term success is subject to many factors that are unpredictable and beyond our control. Investors and prospective investors should consider carefully the following risk factors, in addition to other information contained in this report. This Annual Report on Form 10-K contains forward-looking statements, which are subject to a variety of risks and uncertainties. We have identified below the known, significant risk factors that could affect our business and affect the expectations reflected in our forward-looking statements.

Risks Related to Our Business

We have a history of losses that may continue in the future.

We have reported losses in four of the past five years. Our near-term profitability is challenged by the competitive nature of our industry, continued investment in our operations, and the other risks to our business detailed herein. For example, 2017 represents the third year of a three-year transformation designed to increase growth. There can be no guaranty that we will achieve such growth, or profitability, in the near term. While we believe our capital resources and funds generated by operations are sufficient to operate our business and satisfy our obligations, if unexpected events increase our expenses or harm the performance of our business we may need to seek additional financing. We may also identify opportunities to expand our business that require additional financing. Should we need additional working capital, our ability to raise capital through sales of equity securities depends on general market conditions and the demand for our common stock. We may be unable to raise adequate capital through sales of equity securities, and if our stock has a low market price at the time of such sales our existing stockholders could experience economic dilution. We may also have difficulty obtaining debt financing on acceptable terms or renewing existing debt facilities. An inability to secure additional financing if it is needed in the future could require us to forego opportunities for expansion, or could adversely affect our operations. Also, if we cannot continue to generate positive cash flow from operations, we may have to reduce our costs which could materially and adversely affect our ability to execute our operations and expand our business.

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

Quality system deficiencies observed at certain of our facilities during inspections have led to FDA Warning Letters and delays in product approvals until we resolve FDA concerns. On May 21, 2014, we received the 2014 Warning Letter from the FDA citing alleged violations of cGMP requirements of the Quality System Regulation (QSR) that were identified by the FDA during an inspection of the Company's manufacturing facility in Monrovia, California between February 10, 2014, and March 21, 2014. The 2014 Warning Letter provides that, until we address the deficiencies to the FDA's satisfaction, the FDA will not approve PMAs for the Company's Class III devices where the applications are reasonably related to the cGMP violations cited in the Warning Letter. Beginning on November 14, 2014 and continuing through February 4, 2015, the FDA inspected our Monrovia facility. On February 4, 2015, at the conclusion of the inspection, the FDA issued a Form FDA-483 with ten inspectional observations. The observations focus primarily on the need for adherence to and improved procedures, processes and documentation relating to design change, design transfer into specifications and production, verification and validation associated with device design and production, improvement in good documentation practices, and broader environmental monitoring.

We timely responded to the 2014 Warning Letter and the 2015 FDA-483 and are continuing to implement our corrective action plans related to both issuances and to update FDA monthly on our corrective actions. There can be no assurance when or if the FDA will be satisfied with our response to the 2014 Warning Letter or the 2015 FDA-483 or that FDA will lift the Warning Letter in any specific time frame, if at all. Unless and until STAAR can correct outstanding issues to the FDA's satisfaction, the FDA may withhold approval of new products, such as the TICL. While the TICL PMA supplement remains pending, we cannot predict when, or if, the FDA will grant approval of the TICL for use in the United States. In addition, we may be subject to additional regulatory action by the FDA, including fines, injunctions, warning letters, consent decrees, prosecution, civil money penalties, criminal penalties, repairs, replacements, refunds, recalls or seizures of products, total or partial suspension of production and marketing, the FDA's refusal to grant future premarket approvals, and/or withdrawals or suspensions of approvals or clearance for current products. Any such further action might, ultimately, have a material adverse effect on our ongoing business and operations.

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

We rely and depend on independent distributors in international markets.

Except for the U.S., Japan, Spain, Germany, Canada, and the U.K. we sell our products through independent distributors who generally control the importation and marketing of our product within their territories. We generally grant exclusive rights to these distributors and rely on them to understand local market conditions, to diligently sell our products and to comply with local laws and regulations. Our agreements with distributors and local laws can make it difficult for us to quickly change from a distributor who we feel is underperforming. If we do terminate an independent distributor, we may lose customers who have been dealing with that distributor, and may be required to compensate the distributor for termination. Because these distributors are independent, it may be difficult for us to detect failures in our distributors' performance or compliance. Actions by independent distributors that are beyond our control could result in declining sales in that territory, harm to the reputation of our company or our products, or legal liability. For example, if Shanghai Langsheng, which accounted for 19% of our fiscal 2016 consolidated net sales, ceased to serve as our distributor, or significantly underperform our expectations we may experience a substantial reduction in sales.

Unfavorable economic conditions or negative publicity concerning complications of laser eye surgery hurt sales of our refractive products.

Refractive surgery is an elective procedure generally not covered by health insurance. Patients must pay for the procedure, frequently through installment financing arrangements with third parties. They can defer the choice to have refractive surgery if they lack the disposable income to pay for it or do not feel their income is secure. Economic stagnation, lack of consumer confidence or new recessions in any of our larger markets could slow ICL sales growth or, if severe, cause declines in sales. Because the ICL is our best selling and highest gross margin product, restricted growth or a decline in its sales could materially harm our business.

We believe that negative publicity in the past regarding the potential complications of refractive surgery and potential patient dissatisfaction, in particular because of LASIK and other corneal laser-based procedures, decreased patient interest in LASIK as well as all other refractive procedures. Depending on the nature and severity of any future negative publicity about refractive surgery, the growth of ICL sales could be limited or sales could decline due to decreased patient interest in all refractive surgery.

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

The loss of a material supplier could significantly disrupt our business. In some cases, we obtain components used in certain of our products from single sources. If we experience difficulties acquiring sufficient quantities of required materials or products from our existing suppliers, or if our suppliers are found to be non-compliant with the FDA's QSR, other applicable laws, or STAAR's requirements, then qualifying and obtaining the required regulatory approvals to use alternative suppliers may be a lengthy and uncertain process during which we could lose sales.

Our sources of supply for raw materials may be threatened by shortages and other market forces, by natural disasters, by the supplier's failure to maintain adequate quality or a recall initiated by the supplier. Even when substitute suppliers are available, the need to verify the substitute supplier's regulatory compliance and the quality standards of the replacement material could significantly delay production and materially reduce our sales.

In particular, we manufacture the proprietary collagen-based raw material used in our ICLs, IOLs, and the AquaFLOW Device internally. If the supply of these collagen-based raw materials is disrupted it could result in our inability to manufacture those products and would have a material adverse effect on STAAR. The loss of our external supply source for silicone material, polymer for injectors or acrylic lenses could also, for example, cause us material harm.

Further, any failure by us to forecast demand for or to maintain an adequate supply of, raw material and finished product could result in an interruption in the supply of certain products and a decline in the sales of that product. If our suppliers or we are unable or unwilling to meet our manufacturing requirements, we may not be able to produce enough materials or products in a timely manner, which could cause a decline in our sales.

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

Activities outside the U.S. accounted for approximately 88% of our total sales during 2016. Foreign currency fluctuations could result in volatility of our revenue. The results of operations and the financial position of our Japanese subsidiary are reported in Japanese yen and then translated into U.S. dollars at the applicable exchange rates for inclusion in our consolidated financial statements, exposing us to translation risk. In addition, we are exposed to transaction risk because some of our sales and expenses are incurred in a currency different from the U.S. dollar. Our most significant currency exposures are to the Japanese yen, the euro, and the Swiss franc, and the exchange rates between these currencies and the U.S. dollar may fluctuate substantially. We do not actively hedge our exposure to currency rate fluctuations. Also, we price some of our products in U.S. dollars, and thus changes in exchange rates can make our products more expensive in some offshore markets and reduce our sales. Inflation in emerging markets could also make our products more expensive and increase the credit risks to which we are exposed. Future foreign currency fluctuations could favorably or unfavorably impact and increase the volatility of our revenue, profitability, and stock price.

Economic, social, and political conditions, laws, practices, and local customs vary widely among the countries in which we sell our products. Our operations outside of the U.S. face a number of risks and potential costs, enjoy less stringent protection of intellectual property, and face economic, political, and social uncertainty in some countries, especially in emerging markets. Our continued success as a global company depends, in part, on our ability to develop and implement policies and strategies that are effective in anticipating and managing these and other risks in the countries where we do business. These and other risks may have a material adverse effect on our operations in any particular country and on our business as a whole. For example, sales in certain Asian and developing markets may result in lower margins and higher exposure to intellectual property infringement or counterfeits. Further, trade disputes between the United States and its significant trading partners may adversely affect sales.

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

We have accumulated approximately $136.1 million of U.S. federal tax net operating loss carryforwards as of December 30, 2016, which can be used to offset taxable income in future quarters if our U.S. operations become profitable. If unused, these tax loss carryforwards will begin to expire between 2020 and 2036. At this time, we do not believe our U.S. operations will generate sufficient profitability during the near term to enable us to use the totality of our net operating loss carryforwards before they expire. Also, currently if we generate profits on a consolidated basis, those profits are expected to be primarily generated outside the U.S. and subject to income taxes, cannot be offset with U.S. loss carryforwards. If profits occur in the U.S. this will enable us to begin using our tax loss carryforwards in the U.S., but unexpected changes in tax laws could prevent or hinder us from realizing the benefits of the U.S. loss carryforwards. Moreover, under the current tax laws, if we were to experience a significant change in ownership, Internal Revenue Code Section 382 may restrict the future utilization of these tax loss carryforwards even if our U.S. operations generate significant profits.

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

We depend on the continuing operation of our manufacturing facility in Monrovia, California, which is currently our sole manufacturing facility for ICLs and IOLs. Our Monrovia facility could suffer catastrophic loss due to fire, flood, earthquake, terrorism or other natural or man-made disasters (including manufacturing challenges such as equipment failure) and we would need resources (personnel and equipment) as well as additional regulatory approvals to manufacture our product at any second manufacturing site. Our California and Japanese facilities are in areas where earthquakes could cause catastrophic loss.

Also, in our major markets, regulatory approval to manufacture materials and sell our products is generally limited to the current manufacturing site, and changing the site requires applications to and approval from regulatory bodies prior to commercialization. To satisfy our own quality standards as well as regulations, we must follow strict protocols to confirm that products and materials made at a new site are equivalent to those made at the currently approved site. Even minor changes in equipment, supplies or processes require validation. Unanticipated delays or difficulties in manufacturing a transferred process or materials could interrupt our supply of products. Any sustained interruption in supply could cause us to lose market share and harm our business.

If any of our facilities were to experience a catastrophic loss, or if one of our facilities is found not to be in compliance with regulatory requirements, it could disrupt our operations, delay production, shipments and revenue and result in large expenses to repair or replace the facility, as well as lost customers or sales. Our insurance for property damage and business interruption may not be sufficient to cover any particular loss. We do not carry insurance or reserve funds for interruptions or potential losses arising from earthquakes or terrorism.

We depend on key employees.

We depend on the continued service of our senior management and other key employees. The loss of a key employee could hurt our business. It could be particularly detrimental if any key employee or employees went to work for a competitor. Also, our future success depends on our ability to identify, attract, train, motivate and retain other highly skilled personnel. Failure to do so may adversely affect our results. We do not maintain insurance policies to cover the cost of replacing the services of any of our key employees who may unexpectedly die or become disabled.

We compete with much larger companies.

Our competitors, including Novartis (formerly Alcon), Abbott (formerly Advanced Medical Optics, or AMO) and Valeant (formerly Bausch & Lomb), have much greater financial resources than we do and some of them have large international markets for a full suite of ophthalmic products. Their greater resources for research, development and marketing, and their greater capacity to offer comprehensive products and equipment to providers, makes for intense competition. Over the past several years, we have lost market share in IOL sales to some of our competitors. In addition, start-up competitors from Asia are beginning to appear in some markets with their low-cost version of an implantable contact lens, which competes with our ICL.

Non-compliance with anti-corruption laws could lead to penalties or harm our reputation.

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

We could experience losses due to product liability claims.

We have been subject to product liability claims in the past and may experience such claims in the future. Product liability claims against us may exceed the coverage limits of our insurance policies or cause us to record a loss in excess of our deductible. A product liability claim that exceeds our insurance coverage could materially harm our business, financial condition, and results of operations. Even if an insurance policy covers a product liability loss, we must generally pay for losses until they reach the level of the policy's stated deductible or retention amount after which the insurer begins paying. The payment of retentions or deductibles for a significant number of claims could have a material adverse effect on our business, financial condition, and results of operations.

Any product liability claim would divert managerial and financial resources and could harm our reputation with customers. We cannot assure you that we will not have product liability claims in the future or that such claims would not have a material adverse effect on our business.

Our defined benefit pension plans are currently underfunded and we may be subject to significant increases in pension benefit obligations under those pension plans.

We sponsor two defined benefit pension plans through our wholly owned Swiss and Japanese subsidiaries, which we refer to as the Swiss Plan and the Japan Plan, respectively. Both plans are underfunded and may require significant cash payments.

We determine our pension benefit obligations and funding status using many assumptions. If the investment performance does not meet our expectations, or if other actuarial assumptions are modified, or not realized, we may be required to contribute more than we currently expect and increase our future pension benefit obligations to be funded from our operations.

Our pension plans taken together are underfunded by approximately $4.0 million ($1.2 million for the Japan Plan and $2.8 million for the Swiss Plan) as of December 30, 2016.

If our cash flow from operations is insufficient to fund our worldwide pension obligations, we may be materially and adversely harmed and have to seek additional capital.

Our activities involve hazardous materials, emissions, and use of an irradiator and may subject us to environmental liability.

Our manufacturing, research and development activities involve the use of hazardous materials and equipment. Federal, state and local laws and regulations govern the use, manufacturing, storage, handling and disposal of these materials and certain waste products in the places where we have operations. We cannot eliminate the risk of accidental contamination or injury from these materials and equipment. Remedial environmental actions could require us to incur substantial unexpected costs, which could materially and adversely affect our results of operations. If we were involved in an environmental accident or found to be in substantial non-compliance with applicable environmental laws, we could be held liable for damages or penalized with fines.

If we are unable to protect our information systems against data corruption, cyber-based attacks or network security breaches, our operations could be disrupted.

We depend on information technology networks and our information technology infrastructure for electronic communications among our locations around the world and between our personnel and our subsidiaries, customers, and suppliers. The integrity and protection of our customer, vendor, supplier, employee, and other Company data, is an important part of our business. Addressing applicable security and privacy regulations may increase our operating costs or adversely affect our business operations.

Unauthorized parties may also attempt to gain access to our systems or facilities. Security breaches could disrupt our operations, and result in lost or misappropriated information. Despite the security measures we have in place, our facilities and systems, and those of our suppliers, distributors and customers with whom we do business, may be vulnerable to security breaches, cyber-attacks, or other similar events. Any security breach of Company information, could have a material adverse effect on our business, results of operations and financial condition. Also, certain of our information technology systems are not redundant, and our disaster recovery planning is not sufficient for every eventuality. Despite any precautions we may take, such events could harm our reputation and financial results.

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

New technologies are increasingly used to communicate about our products and the health conditions they are intended to treat. The use of these media requires specific attention and monitoring. For example, patients, competitors, or others may use these channels to comment on the safety or effectiveness of a product and to report an alleged adverse event. Negative posts or comments about us or our business on any social networking web site could harm our reputation. In addition, our employees may use social media tools and mobile technologies inappropriately,

which may give rise to liability, or which could lead to the exposure of sensitive information. In either case, such uses of social media and mobile technologies could have a material adverse effect on our business, financial condition, and results of operations.

Acquisitions of technologies, products, and businesses could disrupt our operations, involve increased expenses and present risks not contemplated at the time of the transactions.

We may consider and, as appropriate, make acquisitions of technologies, products, and businesses that we believe are complementary to our business. Acquisitions typically entail many risks and could result in difficulties in integrating the operations, personnel, technologies, and products acquired, and mitigating the risk of unknown liabilities some of which may result in significant charges to earnings.

If we are unable to successfully integrate our acquisitions with our existing business, we may not obtain the advantages that the acquisitions were intended to create, which may materially adversely affect our business, and our ability to develop and introduce new products. Actual costs and sales synergies, if achieved at all, may be lower than we expect and may take longer to achieve than we anticipate. Furthermore, the products of companies we acquire may overlap with our products or those of our customers, creating conflicts with existing relationships or with other commitments that are detrimental to the integrated businesses.

Risks Related to the Ophthalmic Products Industry

If we fail to keep pace with advances in our industry or fail to persuade physicians to adopt the new products we introduce, customers may not buy our products and our sales may decline.

Our future growth depends, in part, on our ability to develop products to treat diseases and disorders of the eye that are more effective, safer, or incorporate emerging technologies better than our competitors' products, and accepted by physicians and patients. Sales of our existing products may decline rapidly if one of our competitors introduces a superior product, or if we announce a new product of our own. If we focus on technologies that do not lead to better products, more effective or advanced products could surpass our current and planned products. In addition, we must manufacture these products economically and market them successfully by demonstrating to enough eye-care professionals the overall benefits of using them.

Resources devoted to research and development may not yield new products that achieve regulatory approval or commercial success.

Development of new implantable technology, from discovery through testing and registration to initial product launch, is expensive and time-consuming. Because of the complexities and uncertainties of ophthalmic research and development, products we are currently developing may not complete the development process or obtain the regulatory approvals required for us to market the products successfully. Any of the products currently under development may fail to become commercially successful.

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

We are regulated by regional, national, state and local agencies in the U.S. as well as governmental authorities in those international countries in which we manufacture or distribute products, such as in Europe and Asia. The countries' regulations govern the research, development, manufacturing, and commercial activities relating to medical devices, including their design, pre-clinical and clinical testing, clearance or approval, production, labeling, sale, distribution, import, export, post-market surveillance, advertising, dissemination of information and promotion.

Complying with government regulation substantially increases the cost of developing, manufacturing and selling our products.

Competing in the ophthalmic products industry requires us to introduce new or improved products and processes continuously, and to submit these to the FDA and other regulatory bodies for clearance or approval. Obtaining clearance or approval can be a long and expensive process, and clearance or approval is never certain. For example, the FDA or another country's regulatory agency, could require us to conduct an additional clinical trial prior to granting clearance or approval of a product and such clinical trial could take a long time and have substantial expense. In addition, our operations are subject to periodic inspection by the FDA and international regulators. An unfavorable outcome in an FDA inspection may result in the FDA ordering changes in our business practices or taking other enforcement action, which could be costly and severely harm our business.

If a regulatory authority delays approval of a potentially significant product, the potential sales of the product and its value to us can be substantially reduced. Even if the FDA or another regulatory agency clears or approves a product, the clearance or approval may limit the indicated patient populations or uses of the product, or may otherwise limit our ability to promote, sell and distribute the product, or may require post-marketing studies or surveillance. If we cannot obtain timely regulatory clearance or approval of our new products, or if the clearance or approval is too narrow, we will not be able to successfully market these products, which would eliminate or reduce our potential sales and earnings.

In addition, the FDA and other regulatory authorities may change their clearance and approval policies, adopt additional regulations, or revise existing regulations, or take other actions which may prevent or delay approval or clearance of our products under development or impact our ability to modify our currently cleared products on a timely basis.

We depend on proprietary technologies, but may not be able to protect our intellectual property rights adequately.

We rely on patents, trademarks, trade secrecy laws, contractual provisions and confidentiality procedures and copyright laws to protect the proprietary aspects of our technology. These legal measures afford limited protection and may not prevent our competitors from gaining access to our intellectual property and proprietary information. Any of our patents may be challenged, invalidated, circumvented or rendered unenforceable. Any of our pending patent applications may fail to result in an issued patent or fail to provide meaningful protection against competitors or competitive technologies. Litigation may be necessary to enforce our intellectual property rights, and to protect or determine the validity and scope of our proprietary rights. Any litigation could result in substantial expense, may reduce our profits, and may not adequately protect our intellectual property rights. In addition, we may be exposed to future litigation by third parties based on claims that our products infringe their intellectual property rights. This risk is exacerbated by the fact that the validity and breadth of claims covered by patents in our industry may involve complex legal issues that are open to dispute. Any litigation or claims against us, whether or not successful, could result in substantial costs and harm our reputation.

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

As our patents expire, some of which expired over the past several years, our competitors may introduce products using the same technology. Because of this possible increase in competition, we may lose sales and/or may need to reduce our prices to maintain sales of our products, which would make them less profitable. If we fail to develop and successfully launch new products and/or obtain new patents, our sales and profits with respect to our products could decline significantly. We may not be able to develop and successfully launch more advanced replacement products.

Laws pertaining to healthcare fraud and abuse could materially adversely affect our business, financial condition, and results of operations.

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

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

We have voluntarily recalled our products in the past and similar recalls could take place again. We may also be subject to recalls initiated by manufacturers of products we distribute. We cannot eliminate the risk of a material recall in the future. Recalls can result in lost sales of the recalled products themselves, and can result in further lost sales while replacement products are manufactured, especially if the replacements must be redesigned and/or approved by regulatory authorities prior to distribution. If recalled products have already been implanted, we may bear some or all the cost of corrective surgery. Recalls may also damage our professional reputation and the reputation of our products. The inconvenience caused by recalls and related interruptions in supply, the underlying causal issues, and the damage to our reputation, could cause professionals to discontinue using our products.

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

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

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

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

enforcement actions and harm to our results.

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

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

Modifications to our products may require new marketing clearances or approvals, or may require us to cease marketing or recall the modified products until clearances or approvals are obtained.

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

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

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Investigations and allegations, whether or not they lead to enforcement action or litigation, can materially harm our business and our reputation.

Failure to comply with the requirements of the FDA or other regulators can result in civil and criminal fines, the recall of products, the total or partial suspension of manufacturing or distribution, seizure of products, injunctions, lawsuits, failure to obtain approval of pending product applications, withdrawal of existing product approvals, exclusion from participation in government healthcare programs and other sanctions. Any threatened or actual government enforcement action can also generate adverse publicity and require us to divert substantial resources from more productive uses in our business. Enforcement actions could affect our ability to distribute our products commercially and could materially harm our business.

In addition, negative publicity about investigations or allegations of misconduct, even without a finding of misconduct, could harm our reputation with professionals and the market for our common stock. Responding to investigations or conducting internal investigations can be costly, time-consuming, and disruptive to our business.

Risks Related to Ownership of Our Common Stock

The market price of our common stock is likely to be volatile.

Our stock price has fluctuated widely. The closing price of our common stock ranged from $5.12 to $11.45 per share during the year ended December 30, 2016. Our stock price could continue to experience significant fluctuations in response to factors such as market perceptions, quarterly variations in operating results, operating results that vary from the expectations of securities analysts and investors, changes in financial estimates, changes in market valuations of competitors, announcements by us or our competitors of a material nature, additions or departures of key personnel, future sales of our common stock and stock volume fluctuations. Also, general political and economic conditions such as recession or interest rate fluctuations may adversely affect the market price of our common stock.

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

We have not paid any cash dividends on our common stock since our inception. We currently expect to retain any earnings for use to further develop our business, and do not expect to declare cash dividends on our common stock in the foreseeable future. The declaration and payment of any such dividends in the future depends upon our earnings,

financial condition, capital needs, and other factors deemed relevant by the Board of Directors, and may be restricted by future agreements with lenders. As a result, the success of an investment in our common stock will depend entirely upon any future appreciation. There is no guarantee that our common stock will appreciate in value or even maintain the price at which stockholders have purchased their shares.

Our Certificate of Incorporation and Bylaws, anti-takeover provisions of Delaware law, and contractual provisions could delay or prevent an acquisition or sale of our company.

Our Certificate of Incorporation empowers the Board of Directors to issue one or more series of preferred stock, and to determine the rights of each such series as provided in our Certificate of Incorporation. These provisions give the Board of Directors the ability to deter, discourage or make more difficult a change in control of our company, even if such a change in control could be deemed in the interest of our stockholders or if such a change in control would provide our stockholders with a substantial premium for their shares over the then-prevailing market price for the common stock. Our Certificate of Incorporation and Bylaws contain other provisions that could have an anti-takeover effect, including the following:

- stockholders cannot act by written consent;
- certain limitations on stockholder action can be changed only by a 66-2/3% supermajority vote of stockholders; and
- stockholders must give advance notice to nominate directors or propose other business.
- In addition, we are generally subject to the anti-takeover provisions of Section 203 of the Delaware General Corporation Law, which regulates corporate acquisitions. These provisions could discourage potential acquisition proposals and could delay or prevent a change in control transaction. They could also have the effect of discouraging others from making tender offers for our common stock or prevent changes in our management.

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

Our Board of Directors could issue additional shares of common or preferred stock to raise additional capital or for other corporate purposes without stockholder approval. In addition, the Board of Directors could designate and sell a class of preferred stock with preferential rights over the common stock with respect to dividends or other distributions. Also, we have filed a universal “shelf registration statement” with the Securities and Exchange Commission. The shelf registration statement covers the future public offering and sale of up to $200 million in equity or debt securities or any combination of such securities. Sales of common or preferred stock under the shelf registration or in other transactions could dilute the interest of existing stockholders and reduce the market price of our common stock. Even in the absence of such sales, the perception among investors that additional sales of equity securities may take place could reduce the market price of our common stock.

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

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

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

Our operations are conducted in leased facilities throughout the world. Our executive offices, manufacturing, warehouse and distribution, are in Monrovia, California. STAAR Surgical AG maintains office, manufacturing capabilities, warehouse and distribution facilities in Nidau, Switzerland. The Company leases a research and development facility in Tustin, California and has a facility in Aliso Viejo, California for raw material production and research and development activities. STAAR Japan maintains executive offices in Shin-Urayasu, Japan and a final packaging and inspection and distribution facility in Ichikawa City, Japan. We believe our operating facilities in the U.S., Switzerland and Japan are suitable and adequate for our current and future planned requirements. The Company could increase capacity in our Monrovia, California facility by adding additional shifts.

Item 3. Legal Proceedings

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

Item 4. Mine Safety Disclosures

None.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters, and Issuer Purchases of Equity Securities

Market Information

Our common stock is traded on the Nasdaq Global Market (NASDAQ) under the symbol "STAA." The following table sets forth the high and low per share sale prices of our common stock as reported by NASDAQ.

Period	High	Low
Year ended December 30, 2016		
Fourth Quarter	$11.45	$8.20
Third Quarter	9.64	5.61
Second Quarter	7.97	5.12
First Quarter	7.60	6.17
Year ended January 1, 2016		
Fourth Quarter	$8.94	$7.14
Third Quarter	9.61	6.93
Second Quarter	10.63	7.29
First Quarter	9.09	5.71

Holders

As of February 22, 2017, there were approximately 365 record holders of our Common Stock.

Dividends

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

restricted by future agreements with lenders.

Stock Performance Graph

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

The following graph shows a comparison from December 31, 2011 through December 30, 2016 of the total performance of the following:

- STAAR Surgical Company;

- the Nasdaq Stock Market;

- a peer group we have selected consisting of seven companies within our industry or closely related industries: Anika Therapeutics (ANIK); Cutera Inc. (CUTR); Cynosure Inc. (CYNO); Integra LifeSciences Holdings Corp. (IART); Iridex Corp. (IRIX); Merit Medical Systems, Inc. (MMSI); and Syneron Medical Ltd. (ELOS). Volcano Corporation (VOLC) and Synergetics USA Inc. (SURG) were previously included in the peer group, but both were acquired and are no longer independent public companies.

Returns in the graph below reflect historical results; we do not intend to suggest they predict future performance. The data assumes $100 was invested on December 30, 2011 in STAAR common stock and in each of the composite indices, and that dividends (if any) were reinvested. We have never paid dividends on our common stock and have no present plans to do so.

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

Notes:

A. The lines represent monthly index levels derived from compounded daily returns that include all dividends.
B. These indexes are reweighted daily, using the market capitalization from the previous trading day.
C. If the monthly interval, based on the fiscal year-end, is not a trading day, the preceding trading day is used.
D. The index level for all series was set to $100.00 on 12/30/2011.

Item 6. Selected Financial Data

The following table sets forth selected consolidated financial data with respect to the five most recent fiscal years ended December 30, 2016, January 1, 2016, January 2, 2015, January 3, 2014, and December 28, 2012. The selected consolidated statement of operations data set forth below for each of the three most recent fiscal years, and the selected consolidated balance sheet data set forth below at December 30, 2016 and January 1, 2016 are derived from our consolidated financial statements, which have been audited by BDO USA, LLP, our independent registered public accounting firm, as indicated in their report included in this Annual Report. The selected consolidated statement of operations data set forth below for each of the two fiscal years in the periods ended January 3, 2014 and December 28, 2012 and the consolidated balance sheet data set forth below at January 2, 2015, January 3, 2014 and December 28, 2012 are derived from audited consolidated financial statements of the Company not included in this Annual Report. The selected consolidated financial data should be read in conjunction with the consolidated financial statements of the Company, and the Notes thereto, included in this Annual Report, and "*Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.*"

December 30, 2016 &