STAAR SURGICAL CO
Form 10-K
March 13, 2015

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K

(Mark One)

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

For the fiscal year ended January 2, 2015
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. Yes ¨ No þ

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 4, 2014, the last business day of the registrant's most recently completed second fiscal quarter, was approximately $542,806,000 based on the closing price per share of $14.15 of the registrant's Common Stock on that date.

The number of shares outstanding of the registrant's Common Stock as of March 11, 2015 was 38,797,569.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement relating to its 2015 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. 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," "project," "intend," "plan," "believe," "will," "target," "forecast" and similar expressions in connection with any of future operating or financial performance. STAAR Surgical Company cautions investors and prospective investors that any such forward-looking statements are not guarantees of future performance and involve risks and uncertainties, and that actual results may differ materially from those projected in the forward-looking statements. See "Item 1A. Risk Factors."

Item 1. Business

STAAR Surgical Company designs, develops, manufactures and sells implantable lenses for the eye and delivery systems used to deliver the lenses into the eye. We are the leading maker of lenses used worldwide in corrective or "refractive" surgery, and we also make lenses for use in surgery that treats cataracts. All of the lenses we make are foldable, which permits the surgeon to insert them through a small incision during minimally invasive surgery.

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.

STAAR®, Visian®, Collamer®, CentraFLOW®, AquaPORT®, nanoFLEX® nanoPOINT™, Epiphany® and AquaFlow™ are trademarks or registered trademarks of STAAR in the United States (U.S.) and other countries. Collamer® is the brand name for STAAR's proprietary collagen copolymer lens material.

A glossary explaining many of the technical terms used in this report begins on page 14. The reader may also find it helpful to refer to the discussion of the structure and function of the human eye that begins on page 3.

Operations

STAAR has significant operations globally. Activities outside the U.S. accounted for 85% of our total sales in fiscal year 2014, primarily due to the pacing of product approvals and commercialization that tend to occur first outside the U.S. STAAR sells its products in more than 60 countries, with direct distribution in the United States, Canada, Japan and Spain, and independent distribution in the remainder of the world.

STAAR maintains operational and administrative facilities in the United States, Switzerland and Japan. In June 2014 STAAR completed a project to consolidate substantially all of its manufacturing in its Monrovia, California facility. Its current global operations are as follows:

- *United States.* STAAR operates its global administrative headquarters and a manufacturing facility in Monrovia, California. The Monrovia manufacturing facility principally makes Collamer and silicone intraocular lenses (IOLs), and injector systems for its IOLs. We also manufacture the Visian implantable Collamer lenses (ICLs) and preloaded IOL injectors. STAAR manufactures the raw material for Collamer lenses (both IOLs and ICLs) and the AquaFlow Device (for the treatment of glaucoma) in a facility in Aliso Viejo, California.

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

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

The global nature of STAAR's business operations subjects it to risks, including the effect of changes in currency exchange rates, differences in laws, including laws protecting intellectual property and regulating medical devices, political risks and the challenge of managing foreign subsidiaries. Our global manufacturing consolidation also exposes us to the risk of unexpected costs and possible supply interruptions. See "*Item 1A. Risk Factors —Risks Related to Our Business —The global nature of our business may result in fluctuations and declines in our sales and profits"; "—The success of our international operations depend on our successfully managing our foreign subsidiaries"; "—Non-compliance with anti-corruption laws could lead to penalties or harm our reputation"; and "—We may not realize the expected benefits of our manufacturing consolidation and tax strategies."*

The Human Eye

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

The anterior segment consists of the cornea, the iris and ciliary body and the trabecular meshwork. It is filled with a watery fluid called aqueous humor and is divided, by the iris, into an anterior chamber and a posterior chamber. The cornea is the clear window in the front of the eye through which light first passes. The interior surface of the cornea is lined with a single layer of flat, tile-like endothelial cells, whose function is to maintain the transparency of the cornea. The iris is a pigmented muscular curtain located behind the cornea which opens and closes to regulate the amount of light entering the eye through the pupil, an opening at the center of the iris. The natural lens is a clear structure located behind the iris that changes shape to focus light to the retina, located in the back of the eye. The medical term for the natural lens that is present in the eye from birth is "crystalline lens." The trabecular meshwork, a drainage channel located between the iris and the surrounding white portion of the eye, maintains a normal pressure in the anterior chamber of the eye by draining excess aqueous humor.

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

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

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

Financial Information about Segments and Geographic Areas

STAAR's principal products are ICLs and IOLs used in ophthalmic surgery. Because STAAR generates 100% of its sales from the ophthalmic surgical product segment, it operates as one operating segment for financial reporting purposes. 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 have the following goals:

· To improve patient outcomes;

· To minimize patient risk; and

· To simplify ophthalmic procedures or post-operative care for the surgeon and the patient.

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

The ICL folds for minimally invasive implantation behind the iris and in front of the natural crystalline lens, using techniques similar to those used to implant an IOL during cataract surgery, except that the natural lens remains intact in the eye. Lenses of this type are generically called “phakic IOLs” or “phakic implants” because they work along with the patient’s natural lens, or *phakos*, rather than replacing it. The surgeon typically implants the ICL using topical anesthesia on an outpatient basis. The patient usually recovers vision within one to 24 hours.

The ICL is the only posterior chamber phakic IOL (PIOL) approved for sale in the U.S., and we believe it is the world’s largest selling phakic IOL. We believe that our leadership in commercializing this technology results from a number of factors, including proprietary design features and the biocompatibility of the patent-protected Collamer material. STAAR believes that the biocompatibility of the Collamer material used for the ICL (and Toric ICL – TICL, which also corrects for astigmatism) is a significant factor in the ability to place this lens safely in the posterior chamber of the eye. Compared to lenses placed in the anterior chamber, we believe that placement in the posterior chamber provides superior optical results and superior cosmetic appearance, and poses less risk of damage to the cornea.

The ICL has been implanted into more than 500,000 eyes worldwide. The FDA approved the ICL for myopia for use in the U.S. in December 2005. In September 2011, STAAR launched the ICL with CentraFLOW technology, which uses a proprietary port in the center of the ICL optic. The port is of a size intended to optimize the flow of fluid within the eye without affecting the quality of vision, and eliminates the need for the surgeon to perform a YAG peripheral iridotomy procedure days before the ICL implant. By simplifying the procedure and increasing patient comfort, the CentraFLOW technology makes the visual outcomes of the ICL available through a surgical implantation experience closer to LASIK. Outside the U.S., countries where we may sell the ICL and the TICL, which corrects for both astigmatism and myopia, include the following: the countries that require the European Union CE Mark, China, Canada, Korea, Japan, India, Brazil, the Middle East and Singapore. We sell the ICL with CentraFLOW technology in countries that require the European Union CE Mark, China, Korea, Japan, India and certain countries in the Middle East. STAAR submitted its application for U.S. approval of the TICL to the FDA in 2006 which is currently under review (see *“Regulatory Matters – Regulatory Requirements in the United States – Status of Toric ICL Submission”*).

The Hyperopic ICL, which treats far-sightedness, is approved for use in countries that require the European Union CE Mark and in Canada.

The ICL is available for myopia in the United States in four lengths and 27 powers for each length. Outside the U.S., the ICL is available for myopia and hyperopia and is available in multiple models and lengths totaling hundreds of different types of inventoried lenses. This requires us to carry a significant amount of inventory to meet the customer preference for rapid delivery. Outside the U.S. the Toric ICL is available for myopia and hyperopia in the same powers and lengths and also carries additional parameters of cylinder and axis. As a result, we often make the Toric ICL to order, though we were still able to ship approximately 76% in less than one week from receipt of an order at our manufacturing facility.

Sales of ICLs (including TICLs) accounted for approximately 59% of our total sales in fiscal 2014, 61% of our total sales in fiscal 2013, and 55% of our total sales in fiscal 2012.

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 an incision less than 3mm in length, and for one model as small as 2.2 mm. 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 countries government agencies reimburse the cost of cataract surgery and IOLs. Some countries permit ophthalmic surgeons and surgical centers to collect an additional fee from the cataract patient for products and services that go beyond standard treatment. STAAR offers IOLs that fall within the categories that offer an opportunity to increase average selling prices. For example, the U.S. Center for Medicare and Medicaid Services (CMS) allows the provider to receive an additional payment from the patient for the premium lens and associated services. STAAR’s Toric IOL falls in this category.

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, gives 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 and can be delivered through a 2.2 mm micro-incision using STAAR's nanoPOINT Injection System.

We have developed and currently market, principally in the U.S., the Toric IOL, a toric version of our single-piece silicone IOL, which is specifically designed for cataract patients who also have pre-existing astigmatism.

Also, in Japan and 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. In China, we sell a "Preloaded Injector" with a silicone 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. Our agreement with the supplier provides for the sale of the acrylic Preloaded Injector in additional territories by mutual agreement of the two companies.

Sales of IOLs accounted for approximately 32% of our total sales in fiscal 2014, 33% of our total sales in fiscal 2013, and 41% of our total sales in fiscal 2012.

Other Surgical Products

We also sell other related instruments and devices that we manufacture or that are manufactured by others, but these products have relatively lower overall gross profit margins. Also, we sell injector parts to our lens supplier for their preloaded acrylic IOL that they sell under their own brand. Sales of other surgical products accounted for approximately 9% of our total sales in fiscal 2014, 5% of our total sales in fiscal 2013, and 4 % of our total sales in fiscal 2012.

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 although we do not typically pursue regulatory and quality certification of multiple sources of supply.

Patents, Trademarks and Licenses

We strive to protect our investment in the research, development, manufacturing and marketing of our products through the use of patents, licenses, trademarks, copyrights, and trade secrets. We own or have rights to a number of patents, licenses, trademarks, copyrights, trade secrets and other intellectual property directly related and important to our business. As of January 2, 2015, we owned approximately 67 United States and foreign patents and had approximately 21 patent applications pending. In addition, as of January 2, 2015, our Japanese subsidiary owned approximately 50 Japanese and foreign patents and had approximately 2 patent applications pending.

We consider our patents to be significant when they protect the exclusivity of our material products in the marketplace or provide an opportunity to obtain material royalties or cross-licenses of intellectual property from other manufacturers. Because we have limited knowledge of the research and development efforts and strategic plans of our competitors, we can only estimate the value of our patents and the significance of any particular patent’s expiration. Competitors may be able to design products that avoid infringing on patents that we regard as valuable, or they may find patents that we regard as less significant to be obstacles to their development of competing products. Our internal assessments of our patents include confidential information, the disclosure of which would cause significant competitive harm to STAAR.

Our material patents generally fall within three areas of technology: (1) design of a posterior chamber phakic intraocular lens used to treat refractive errors of the eye (ICLs); (2) the Collamer lens material; and (3) lens delivery systems for folding intraocular lenses (injectors and cartridges, both stand-alone and preloaded, used with ICLs and IOLs).

STAAR has several patents covering design features that we believe are important to the safety and effectiveness of its ICLs, and that we believe would be necessary or desirable for any competing posterior chamber phakic IOL. Some of these patents expire by the end of 2016. Collamer belongs to a family of materials known as *collagen copolymers*. Collagen copolymers are compounds formed by joining molecules of collagen derived from biological sources with synthetic monomer molecules. The patents that underlie the specific formulation and manufacturing methods for Collamer expire by the end of 2016, with the last blocking patent expiring in 2017. Over the past two years, we have filed patent applications covering new lens designs, and new lens delivery systems.

STAAR also owns numerous patents covering the technology of foldable lens delivery systems, including injectors, cartridges and preloaded injectors and their specific design features. This group of patents includes patents with up to five years of life remaining.

In addition to patents, we possess trade secrets and know-how regarding the design and production of the collamer material and the manufacture of ICLs all of which we perform internally. We believe it would require extensive time and effort for a competitor to duplicate these processes to develop a product with comparable capabilities to the ICL product line.

Worldwide, we sell all of our major products under trademarks we consider to be important to our business. 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.

Seasonality

Seasonality does not materially affect our sales, although the third quarter may be lower due to the summer vacation effect in Europe.

Distribution and Customers

We market our products to a variety of health care providers, including surgical centers, hospitals, managed care providers, health maintenance organizations, group purchasing organizations and government facilities. The primary user of our products is the ophthalmologist.

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

A single customer, WooJeon Medical Co., Ltd., our Korean distributor, accounted for more than 10% of our consolidated net sales during fiscal 2013 and 2012, although this decreased to approximately 9% during fiscal 2014. Net sales to WooJeon during each of the last three fiscal years were as follows:

Net Sales to WooJeon

Fiscal Year	Net Sales ($, in thousands)	Net Sales as Percentage of Consolidated Net Sales
2014	$ 6,563	8.8 %
2013	$ 7,743	10.7 %
2012	$ 6,713	10.5 %

Backlog

The dollar amount of STAAR's backlog orders is not significant in relation to total annual sales. We generally keep sufficient inventory on hand to ship product when ordered.

The ICL is manufactured to address refractive prescriptions across a broad range of correction, resulting in a large number of Stock Keeping Units (SKUs). The challenge of maintaining inventory in all models can result in a backlog in customer orders. In the fourth quarter of 2014, we experienced a backlog for ICLs and TICLs primarily due to manufacturing challenges in our Monrovia facility. Also, we implemented a voluntary hold on over 2,000 ICLs from shipment at the end of the quarter. The impact of these manufacturing challenges to our revenue in the fourth quarter of 2014 was approximately $1.0 million. We continue to address the issues and expect to reduce the backlog to customary levels by the end of the first quarter 2015 or the end of the second quarter. If we cannot resolve our manufacturing challenges in the first quarter of 2015, our financial results may be adversely impacted.

Government Contracts

No material portion of our business is subject to renegotiation of profits or termination of contracts or subcontracts 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 it in the key markets around the world. The development of new or improved products may make existing products less attractive, reduce them to commodity status or even make them obsolete. To remain competitive, companies such as STAAR must devote continued efforts and significant financial resources to enhance their existing products and to develop new products.

In the refractive market, our ICL technology competes with other elective surgical procedures such as laser vision correction or LASIK, for those consumers who are looking for an alternative to eyeglasses or contact lenses to correct their vision.

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 the much better known and widely available laser surgical procedures. Novartis (formerly Alcon), Abbott Medical Optics (formerly Advanced Medical Optics or AMO), and Valeant (formerly Bausch & Lomb or B&L) all market excimer lasers for corneal refractive surgery and promote their sales worldwide.

Phakic implants that compete with the ICL are also available in the marketplace. The three principal types of phakic IOLs (PIOLs) are (1) posterior chamber designs like the ICL, (2) iris clip anterior chamber PIOLs like the Artisan® and Artiflex® lenses made by Ophtec (Artisan® is distributed in the U.S. by AMO under the Verisyse® brand), and (3) angle-supported anterior chamber PIOLs like the Cachet™ made by Alcon and sold outside the U.S. We believe the ICL has compelling clinical advantages over the other lenses, which are reflected in our estimated 75% market share of the global phakic IOL market. The ICL is the only foldable, minimally invasive PIOL approved for sale in the U.S. Start-up competitors from a low cost manufacturing geography are beginning to appear in the market with a low cost alternative to the ICL, though we do not believe they are having a material impact on our sales at this time.

As with the refractive market, the global cataract market is highly concentrated, with the top three competitors (Novartis, Abbott and Valeant) combined accounting for approximately 70% of total market revenue, according to internal estimates and a 2014 report by Market Scope, LLC, a publisher of ophthalmic industry analysis.

Regulatory Matters

Nearly all countries where we sell our products have regulations requiring premarket clearance or approval of medical devices. Various federal, state, local and foreign laws also apply to our operations, including, among other things, working conditions, laboratory, clinical, 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 requirements comparable to those established by the U.S. Food and Drug Administration (FDA). For example, many countries in South America and the Middle East have minimal regulatory requirements, while many others, such as Japan, have requirements of similarly stringency to those of the FDA. Obtaining clearance or approval to distribute medical products is costly and time-consuming in virtually all of the major markets where we sell medical devices.

We cannot give any assurance that any new medical devices we develop will be cleared or approved in a 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. We also cannot give any assurance that if our medical devices are approved for sale in a country 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 and Japan, and in 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, pre-market clearance and approval, recordkeeping, reporting, advertising, promotion, post-market surveillance, and import and export of medical devices.

Most of our products are 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

pre-market approval (PMA) from the FDA, unless specifically exempted by the agency. 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 (pre-market approval (PMA) required before commercial marketing). Devices deemed to pose lower risk are categorized as either Class I or II, which require the manufacturer to submit to the FDA a 510(k) pre-market notification requesting clearance of the device for commercial distribution in the United States. Some low risk devices are exempt from this requirement. Class III devices are deemed by the FDA to pose the greatest risk and are the most extensively regulated. These devices include life-supporting, life sustaining, or implantable devices, or devices deemed not substantially equivalent to a previously 510(k) cleared device. The effect of assigning a device to Class III is to require each manufacturer to submit to the FDA a PMA that includes information on the safety and effectiveness of the device. The FDA reviews device applications and notifications through its Office of Device Evaluation, or "ODE."

510(k) Clearance. Our lens injector systems are Class I devices subject to the 510(k) pre-market 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) pre-market 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) pre-market notifications are cleared without clinical data, in some cases, the FDA requires significant clinical data to support substantial equivalence. In reviewing a pre-market 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 pre-market approval. The FDA requires each manufacturer to make its own initial determination as to whether a change meets this threshold. However, the FDA can review any such decision and can disagree with a manufacturer's determination. If the FDA disagrees with a manufacturer's determination, the FDA can require the manufacturer to cease marketing or recall the modified device until 510(k) clearance or a PMA is obtained. We have modified aspects of some of our devices since receiving 510(k) clearance, and have determined that no new clearance or approval was required. If the FDA requires us to seek 510(k) clearance or pre-market approval for any modifications to a previously cleared product, we may be required to cease marketing or recall the modified device until we obtain this clearance or approval. Also, in these circumstances, we may be subject to significant regulatory fines or penalties.

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

After a PMA application is submitted and filed, the FDA begins an in-depth review of the submitted information, which typically takes between one and three years, but may take significantly longer. During the review period, the FDA may request additional information or clarification of information already provided. In addition to its own review, the FDA may organize an independent advisory panel of experts to review the PMA whenever a device is the first of its kind or the FDA otherwise determines panel review is warranted. The FDA holds panels on a regular basis, but the need to schedule panel review usually adds some weeks or months to the review process. In addition, the FDA will conduct a pre-approval inspection of the manufacturing facility to ensure compliance with Quality System Regulation (QSR) which imposes elaborate design development, testing, control, documentation 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 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 certain changes prior to the FDA's review of the PMA Supplement. The FDA designates some PMA Supplements as "panel track" supplements, which means that the agency believes review by an advisory panel may be warranted. Designation as a panel-track supplement does not necessarily mean that panel review will actually occur.

Clinical or Market Trials. A clinical trial is typically required to support a PMA application and is sometimes required for a 510(k) pre-market notification. Clinical trials generally require submission of an application for an Investigational Device Exemption (IDE) to the FDA. The IDE application must be supported by appropriate data, such as animal and laboratory testing results, showing that it is safe to test the device in humans and that the investigational protocol is scientifically sound. The IDE application must be approved in advance by the FDA for a specified number of patients, unless the product is deemed a non-significant risk device and eligible for more abbreviated IDE requirements. Clinical trials for a significant risk device may begin once the IDE application is approved by the FDA as well as the appropriate institutional review boards (IRBs) at the clinical or market trial sites, and the informed consent of the patients participating in the clinical trial is 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 U.S. 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 and other regulations. Both before and after we receive pre-market 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, and manufacturers' required reports of adverse experiences 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 regulations and requirements, such as restrictions on advertising and promotion. The Good Manufacturing Practice (GMP) regulations for medical devices known as the QSR, govern the methods used in, and the facilities and controls used for, the design, manufacture, packaging 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 and accurate. Another objective of the program is to ensure that human subjects are protected from undue hazard or risk during the course of scientific investigations.

If the FDA were to conclude that we are not in compliance with applicable laws or regulations, or that any of our medical devices are ineffective or pose an unreasonable health risk, the FDA could require us to notify health professionals and others that the devices present unreasonable risk or substantial harm to public health, order a recall, repair, replacement, or refund of the devices, detain or seize adulterated or misbranded medical devices, or ban the medical devices. The FDA may also issue warning letters or untitled letters, refuse our request for 510(k) clearance or PMA approval, revoke existing 510(k) clearances or PMA approvals previously granted, impose operating restrictions, enjoin and restrain certain violations of applicable law pertaining to medical devices and assess civil or criminal penalties against our officers, employees, or us. The FDA may also recommend prosecution to the Department of Justice.

For example, in 2007 we received a warning letter following a BIMO inspection that identified negative inspectional observations. Prior to the inspection and the warning letter, we submitted a PMA supplement for the TICL to the FDA on April 28, 2006, which the agency designated as a panel-track supplement. In August 2007, following negative inspectional observations and the warning letter the FDA Office of Device Evaluation placed an integrity hold on our TICL application. Over a two-year period we took a number of corrective actions to address BIMO's concerns and to remove the integrity hold, including engaging an independent third party to conduct a 100% audit of patient records in the TICL clinical study, along with an audit of clinical systems to ensure accuracy and completeness of data before resubmitting the application. On July 21, 2009, the FDA notified us that as a result of our corrective actions the FDA had removed the integrity hold on the application for approval of the TICL, and would resume its consideration of the application. On February 3, 2010, we received a letter of deficiency from the FDA outlining additional questions. After several communications with the FDA, on November 29, 2011, we received a letter of deficiency from the FDA further questioning the clinical data. After further interactions with the FDA throughout 2012, on November 15, 2012, we submitted (1) clinical data showing no statistical difference in the clinical outcomes with or without patient data that was obtained outside the study windows, (2) engineering data regarding the lens design, and (3) a validation report for the Toric ICL power calculation software. On March 14, 2014 an FDA Ophthalmic Devices Panel of the Medical Devices Advisory Committee that 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 (the "2014 Warning Letter") citing alleged violations of current good manufacturing practice ("cGMP") regulations 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. 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 premarket applications ("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 FDA-483 and is concurrently continuing to develop and implement its corrective action plans relating to the 2014 Warning Letter and the 2015 FDA-483. While the PMA supplement remains pending, we cannot predict when, or if, the FDA will grant approval of the TICL for use in the United States.

Our ability to continue our U.S. business depends on the continuous improvement of our quality systems and our ability to demonstrate compliance with FDA regulations. Accordingly, our management expects to continue to devote significant resources and attention to those efforts for the foreseeable future.

Healthcare Fraud and Abuse Laws and Regulations

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

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

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

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

- the federal physician sunshine requirements under the Health Care Reform Law, 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, 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 Affordable Care Act provides that the government may assert that a claim including items or services resulting from a violation of the Federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act.

Achieving and sustaining compliance with these laws may prove costly. In addition, any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, the exclusion from participation in federal and state healthcare programs, imprisonment, or the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business, our reputation and our financial results.

Regulatory Requirements outside the United States.

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

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