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

Form 10-K

(Mark One)

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

For the fiscal year ended December 31, 2021

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.)*
25651 Atlantic Ocean Drive	
Lake Forest, California	**92630**
(Address of Principal Executive Offices)	*(Zip Code)*

(626) 303-7902

(Registrant's telephone number, including area code)

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common	STAA	NASDAQ

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

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

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

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

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

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

Large accelerated filer	☑	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☐
Emerging growth company	☐		

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

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☑

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant as of July 2, 2021, the last business day of the registrant's most recently completed second fiscal quarter, was approximately $6,858,819,973 based on the closing price per share of $144.73 of the registrant's Common Stock on that date.

The registrant has 47,754,663 shares of common stock, par value $0.01 per share, issued and outstanding as of February 18, 2022.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement relating to its 2022 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," "should," "forecast" and similar expressions in connection with any discussion of future operating or financial performance. STAAR Surgical Company cautions investors and prospective investors that any such forward-looking statements are not guarantees of future performance and involve risks and uncertainties, and that actual results may differ materially from those projected in the forward-looking statements. We caution you not to place undue reliance on these forward-looking statements and to note they speak only as of the date hereof. Factors that could cause actual results to differ materially from those set forth in the forward-looking statements are included in the risk factors set forth in Item 1A, "Risk Factors." We disclaim any intention or obligation to update or revise any financial projections or forward-looking statements due to new information or other events.

ITEM 1. Business

STAAR Surgical Company designs, develops, manufactures, and sells implantable lenses for the eye and delivery systems used to deliver the lenses into the eye. We are the leading manufacturer of lenses used worldwide in corrective or "refractive" surgery. We have been dedicated solely to ophthalmic surgery for over 30 years. Our goal is to position our refractive lenses throughout the world as primary and premium solutions for patients seeking visual freedom from wearing eyeglasses or contact lenses while achieving excellent visual acuity through refractive vision correction. We also make lenses for use in surgery that treats cataracts. Unless the context indicates otherwise, "we," "us," the "Company," and "STAAR" refer to STAAR Surgical Company and its consolidated subsidiaries.

A glossary explaining many of the technical terms used in this report begins on page 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 7.

Operations

STAAR has significant operations globally. Activities outside the United States (U.S.) accounted for 96% of our total sales in fiscal year 2021, primarily due to the pacing of product approvals and commercialization that tend to occur first outside the United States. STAAR sells its products in more than 75 countries, with direct distribution (i.e., via STAAR representatives) in Japan, Germany, Spain, the U.S., Canada, the U.K. and Singapore, with a combination of direct distribution and independent distribution (i.e., via distributors and STAAR representatives) in China, Korea, India, France, Benelux, and Italy, and with independent distribution in the remainder of the countries where we sell.

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

- *United States*. STAAR operates its global administrative offices and principal manufacturing facility in Monrovia, California. The Monrovia manufacturing facility primarily makes the Visian implantable Collamer lens product family, including the EVO Visian ICL (collectively referred to as ICLs), preloaded silicone cataract intraocular lenses (IOLs), and injector systems. We manufacture the raw material for Collamer lenses in our facility in Aliso Viejo, California. STAAR also operates a Technology Center housing its Research & Development team and labs in Tustin, California. STAAR's facility in Lake Forest, California serves as our corporate headquarters. It contains executive offices and operational facilities we expect to use for future manufacturing of STAAR's Presbyopia lenses, EVO *Viva*.
- *Switzerland*. STAAR operates an administrative, distribution and operational facility in Brugg, Switzerland under its wholly owned subsidiary, STAAR Surgical AG. We are in the process of expanding our manufacturing capabilities for STAAR's ICL products in our Nidau, Switzerland facility.
- *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 cataract 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 17 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 and post-operative care for the surgeon and the patient.

EVO Visian ICL, EVO Viva ICL, and Visian ICL. Refractive surgery corrects visual disorders that eyeglasses 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), astigmatism and presbyopia.

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 Food and Drug Administration (FDA) for marketing and sale in the U.S., and we believe it is the world's largest selling phakic IOL. Our biocompatible Collamer material belongs to a family of materials known as collagen copolymers. Collagen copolymers are compounds formed by joining molecules of collagen derived from biological sources with synthetic monomer molecules. The proprietary Collamer material is exclusive to us. We believe that the biocompatibility of the Collamer material used for the ICL product line is a significant factor in the ability to place this lens safely in the posterior chamber of the eye.

The ICL has been implanted into more than 1,000,000 eyes worldwide. STAAR began selling the ICL for myopia for use outside the U.S. in 1997. U.S. sales commenced in 2006. In September 2011, STAAR launched the ICL with CentraFLOW technology, which uses a port in the center of the ICL optic in markets outside the U.S. The port is of a size intended to optimize the flow of fluid within the eye without affecting the quality of vision. The central port also eliminates the need for the surgeon to perform a YAG peripheral iridotomy procedure days before the ICL implant. The CentraFLOW technology makes the visual outcomes of the ICL available through a simpler and more comfortable surgical implantation experience. We are authorized to sell the ICL with CentraFLOW technology in the following ex-U.S. regions: the approximately 31 countries that require the European Union CE Mark, China, Canada, Korea, Japan, India, Argentina, Singapore, and several countries in the Middle East. In December 2015, we received the CE Mark for EVO+, an ICL with CentraFLOW technology and an expanded optical zone of up to 20%. We believe the expanded optical zone may further improve certain patients' visual experience, thus making the ICL increasingly desirable for both patients and ophthalmic surgeons. We are authorized to sell the EVO+ in the following ex-U.S. regions: the approximately 31 countries that require the European Union CE Mark, Korea, Japan, India, Canada, Hong Kong, Turkey, and several countries in the Middle East. The Hyperopic ICL, which treats far-sightedness, is sold primarily in countries that require the European Union CE Mark. In July 2020, we received the CE Mark for EVO *Viva*, a presbyopia-correcting ICL with an aspheric EDOF optic. We commenced a limited launch of the EVO *Viva* lens in Spain, Belgium and Germany. The EVO *Viva* lens adds near and intermediate vision correction for patients with presbyopia. We believe the EVO *Viva* lens will assist certain patients with eliminating the burdens of reading glasses or frequent replacement contact lenses. Typically, ICL surgery is an elective procedure paid for or financed by the patient.

Globally, the ICL is available for myopia and hyperopia and is available in multiple models, powers and lengths totaling hundreds of different types of inventoried lenses. This requires us to carry a significant amount of inventory to meet customer preference for rapid delivery. The Toric ICL (TICL), which also corrects for astigmatism, is

available for myopia in the same powers and lengths and carries additional parameters of cylinder and axis. The EVO *Viva* lens is available for myopia in the same powers and lengths and carries additional parameters relating to presbyopia correction.

According to Market Scope, LLC a publisher of ophthalmic industry data, approximately 4.2 million refractive procedures, primarily laser vision procedures, were performed worldwide in 2021. The incidence of myopia is growing globally, with high myopia becoming more common according to recently published articles, affecting nearly 5 billion and 1 billion people, respectively, by 2050 (Global Prevalence of Myopia and High Myopia and Temporal Trends from 2000 through 2050, *Ophthalmology, Vol. 123, No. 5, May 2016;* Global trends in myopia management attitudes and strategies in clinical practice, *Contact Lens and anterior Eye, Vol. 39, 2016*). We believe this will result in a significantly increased number of patients seeking refractive procedures. We believe that over the past decade negative publicity regarding LASIK has reduced patient interest in the LASIK procedure. The ICL is a lens-based refractive procedure (unlike LASIK) with over 1,000,000 ICLs implanted to date. Surgeons have published over 100 peer-reviewed articles with clinical data regarding the safety, effectiveness, and visual quality of the ICL. We believe the ICL provides a safe and effective solution for the growing number of myopic patients who will seek visual freedom from eyeglasses and contact lenses.

We plan to continue to develop and launch innovative products to support clinical needs and to address the increasing demands of our customers. As part of our sales and marketing efforts, we attend and participate in major ophthalmic conventions around the world and invest in market development, practice support, healthcare professional training and patient outreach. We have started working more closely with leading refractive clinics in the area of training, product awareness and practice development. Our marketing programs seek to position the ICL as a premium and primary option for appropriate patients at the clinic and via digital and social media.

In September 2018, the FDA granted approval of our PMA Supplement for the Visian Toric ICL for the correction of myopia with astigmatism for marketing and sale in the United States. In August 2019, the FDA notified us that it had determined that STAAR had provided sufficient data to support initiation of a human clinical study in the United States of the EVO/EVO+ VISIAN® Implantable Collamer® Lens for Myopia, and EVO/EVO+ VISIAN® Toric Implantable Collamer® Lens for Myopia with Astigmatism. In November 2020, we completed enrollment for the primary study analysis cohort of 300 subjects in our U.S. EVO clinical trial. In April 2021, we submitted clinical data to the FDA to support a marketing approval for our EVO family of myopia lenses. Our submission remains under interactive review with the FDA.

Sales of ICLs (including EVO+ and TICLs) accounted for approximately 92% of our total sales in fiscal 2021, 87% of our total sales in fiscal 2020 and 86% of our total sales in fiscal 2019.

Other Products

Intraocular Lenses (IOLs). We sell in parts of Asia and parts of Europe a "Preloaded Injector" with an acrylic IOL packaged and shipped in a pre-sterilized, disposable injector ready for use in cataract surgery. We also sell a silicone lens-based Preloaded Injector in Japan. 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.

The silicone lens-based Preloaded Injector uses a lens produced and marketed by STAAR. This line of foldable cataract IOLs is manufactured from silicone in a three-piece design with Polyimide loop haptics attached to the optic, they are largely aspheric cataract IOLs that use optical designs that produce a clearer image than traditional spherical lenses, especially in low light.

In most of the countries where STAAR sells cataract IOLs, government agencies reimburse most or all of the cost of cataract surgery and IOLs. Government agencies continue to reduce the reimbursement rates for cataract surgery and IOLs. In response, we continue to assess and rationalize our low margin cataract IOLs. For example, during the fourth quarter of 2019, we decided to phase out our nanoFLEX IOL, a single piece aspheric cataract IOL and to only sell our silicone lens-based Preloaded Injector in Japan.

Sales of cataract IOLs accounted for approximately 6% of our total sales in fiscal 2021, 8% of our total sales in fiscal 2020 and 11% of our total sales in fiscal 2019.

Other Surgical Products. We sell injector parts to our acrylic lens supplier for their preloaded acrylic cataract 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 cataract IOLs. Sales of other surgical products accounted for approximately 2% of our total sales in fiscal 2021, 5% of our total sales in fiscal 2020 and 3% of our total sales in fiscal 2019.

Sources and Availability of Raw Materials

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

Patents, Trademarks, and Licenses

We strive to protect our investment in the research, development, manufacturing, and marketing of our products through the use of patents, trademarks, licenses, trade secrets, and copyrights. We own or have rights to a number of patents, licenses, trademarks, copyrights, trade secrets, know-how and other intellectual property related and important to our business. As of December 31, 2021, we owned approximately 65 United States and foreign patents and had 27 patent applications pending. We rely more on trade secrets than patents and believe that no particular patent is so important that its loss or expiration would materially adversely affect our operations as a whole.

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

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

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

Seasonality

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

Working Capital Requirements

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

Distribution and Customers

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

We sell our products directly through our own sales representatives in Japan, Germany, Spain, the U.S., Canada, the U.K. and Singapore. We sell through a combination of our own representatives and independent distributors in China, Korea, India, France, Benelux, and Italy. We sell through independent distributors in other countries. Our products are sold in more than 75 countries worldwide. We maintain a global marketing team, as well as regional marketing personnel to support the promotion and sale of our products. The global marketing

department supports selling efforts by developing and providing promotional materials, speakers' programs, digital and social media sites, participation in trade shows and technical presentations. Where we distribute products directly, we rely on local sales representatives to help generate sales by promoting and demonstrating our products with physicians. In the U.S., we also rely on independent sales representatives to sell our products under the supervision of directly employed sales managers. Our clinical affairs personnel provide training and educational courses globally.

One customer, Shanghai Lansheng, our China distributor who sells into China and Hong Kong, accounted for approximately 47% of our consolidated net sales during fiscal 2021. Net sales to Shanghai Lansheng during each of the last three fiscal years were as follows:

Net Sales to Shanghai Lansheng

Fiscal Year	Net Sales ($, in thousands)	Net Sales as Percentage of Consolidated Net Sales
2021	$ 107,333	46.6%
2020	$ 71,692	43.9%
2019	$ 64,820	43.2%

Backlog

We generally keep sufficient inventory on hand to ship product immediately or shortly after receipt of an order. 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 2021, COVID-19 related issues and production output challenges impacted us and resulted in backlog of over 20,000 lenses at the end of the fourth quarter. We continue to focus on meeting the significant level of demand for our ICL lenses and achieving standard inventory level requirements in 2022.

Government Contracts

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

Competition

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

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

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

Phakic implants that compete with the ICL are also available in the marketplace. The two principal types of phakic IOLs are (1) posterior chamber designs like the ICL, and (2) iris clip anterior chamber PIOLs like the Artisan® and Artiflex® lenses made by Ophtec. We believe the ICL has compelling clinical advantages over the other lenses, which are reflected in our strong market share of the global phakic IOL market. The ICL is the only foldable, minimally invasive PIOL approved for sale in the U.S. In addition, competitors from Asia are beginning to appear in the market with their low-cost version of a posterior chamber implantable contact lens, increasing the level of competition.

The global cataract IOL market is highly concentrated, with the top five competitors (Alcon, Johnson & Johnson, Hoya, Bausch & Lomb and Carl Zeiss Meditec) combined accounting for approximately 67% of total market revenue, according to a 2021 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, located behind the iris, completes the focusing of light and can change shape to focus objects at different distances onto the retina, located in the back of the eye. The trabecular meshwork, a drainage channel located between the iris and the surrounding white portion of the eye, maintains a normal pressure in the anterior chamber of the eye by draining excess aqueous humor.

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

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

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

Regulatory Matters

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

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

Regulatory Requirements in the United States.

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

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

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

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

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

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

After a PMA application is submitted and filed, the FDA begins an in-depth review of the submitted information, which typically takes between one and three years, but may take significantly longer. During the review period, the FDA may request additional information or clarification of information already provided. In addition to its own review, the FDA may organize an independent advisory panel of experts to review the PMA whenever a device is the first of its kind or the FDA otherwise determines panel review is warranted. The FDA holds panels on a regular basis, but the need to schedule panel review usually adds some weeks or months to the review process. In addition, the FDA will conduct a pre-approval inspection of the manufacturing facility to ensure compliance with Quality System Regulation (QSR) which imposes elaborate design, development, testing, control, validation,

documentation, complaint handling, supplier control, and other quality assurance procedures in the design and manufacturing process. The FDA may approve a PMA application with post-approval conditions intended to ensure the safety and effectiveness of the device including, among other things, restrictions on labeling, promotion, sale and distribution and conduct of additional post-approval clinical studies or collection of long-term follow-up from patients in the clinical study that supported approval. Failure to comply with the conditions of approval can result in materially adverse enforcement action, including the loss or withdrawal of the approval.

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

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

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

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

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

For example, on May 27, 2014, we received a warning letter from the FDA (2014 Warning Letter) citing alleged violations of current good manufacturing practice (cGMP) regulations that were identified by the FDA during an inspection of our manufacturing facility in Monrovia, California between February 10, 2014, and March 21, 2014. On November 14, 2014 and continuing through February 4, 2015, the FDA again inspected our Monrovia facility. On February 4, 2015, at the conclusion of the inspection, the FDA issued an FDA-483 with ten inspectional observations (2015 FDA-483). STAAR responded to the 2014 Warning Letter and the 2015 FDA-483 and implemented its corrective action plans relating to the 2014 Warning Letter and the 2015 FDA-483. On June 19, 2018, we received a close-out letter from the FDA lifting the 2014 Warning Letter.

Healthcare Fraud and Abuse Laws and Regulations.

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

- the federal Anti-Kickback Statute, which prohibits, among other things, any person from knowingly and willfully offering, soliciting, receiving, or providing remuneration, directly or indirectly, to induce either the referral of an individual, for an item or service or the purchasing or ordering of a good or service, for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs;
- the federal False Claims Act, which prohibits, among other things, individuals, or entities from knowingly presenting, or causing to be presented, false claims, or knowingly using false statements, to obtain payment from the federal government, and which may apply to entities that provide coding and billing advice to customers;
- federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- the federal physician sunshine requirements under the Patient Protection and Affordable Care Act of 2010, which requires manufacturers of drugs, devices, biologics, and medical supplies to report annually to the Centers for Medicare & Medicaid Services information related to payments and other transfers of value relating to certain drugs, devices, biologics, and medical supplies to physicians, other healthcare providers, and teaching hospitals, and ownership and investment interests held by physicians and other healthcare providers and their immediate family members;
- the federal Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, which governs the conduct of certain electronic healthcare transactions and protects the security and privacy of protected health information; and
- state and international law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payer, including commercial insurers; state laws that require device companies to comply with the industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state and international laws that require device manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state and international laws governing the privacy and security of health information in certain circumstances, which may differ from each other and may not have the same effect, thus complicating compliance efforts.

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

Regulatory Requirements Outside the United States.

CE Marking. In the European Economic Area (EEA), which is comprised of the 27 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 and the United Kingdom, 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.

The European Union regulatory bodies finalized a new Medical Device Regulation (MDR) in 2017, which replaced the existing Directives and provided three years for transition and compliance. The MDR will change several aspects of the existing regulatory framework, such as updating clinical data requirements and introducing new ones, such as Unique Device Identification (UDI). We and the Notified Bodies who will oversee compliance to the new MDR face uncertainties and increased costs as the MDR is rolled out and enforced by the European Commission and EEA Competent Authorities, creating risks in several areas, including the CE Marking process and data transparency, in the upcoming years. In April 2020, the European Parliament postponed implementation of MDR to May 2021 due to the COVID pandemic. The exit of the UK from the European Union (BREXIT) has resulted in the requirement to re-certify our preloaded acrylic IOL under a non-UK Notified Body, and to separately register our CE Marked products for sale in the UK. The failure of Switzerland and the EU to enter into a Mutual Recognition Agreement resulted in a change of our EC Authorized Representative, discontinuance of the pre-loaded acrylic IOL for the Swiss market, and registration of our remaining products under Swiss law.

We have affixed the CE Mark to all our principal products sold in CE Mark jurisdictions including ICLs, IOLs and injector systems. In July 2017, our Notified Body in the European Union, DEKRA, re-certified the CE Marking for all our currently certified and commercially available medical devices. In March 2018, DEKRA performed audits of our US and Swiss facilities certifying them to EN ISO 13485:2016 as well as to the "Medical Device Single Audit Program" (MDSAP). MDSAP provides for a single audit recognized by Australia, Brazil, Canada, Japan and the United States demonstrating routine compliance with QSR/GMP requirements. DEKRA performed an unannounced audit in December 2018, and surveillance audits in 2019. In 2020, DEKRA audited and approved our new facility in Brugg, Switzerland and completed surveillance audits of all our facilities, reconfirming our compliance to EN ISO 13485:2016 and MDSAP. In 2021, DEKRA conducted audits of our facilities and re-certified them under MDSAP and EN ISO 13485:2016.

Medical Device Regulation in Japan. The Japanese Ministry of Health, Labor, and Welfare (MHLW) regulates the sale of medical devices under Japan's Pharmaceuticals and Medical Devices Act (PMD Act). The Pharmaceuticals and Medical Devices Agency (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* (premarket 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 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 PMDA 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 the PMD Act. STAAR is subject to inspection for compliance by these agencies. A company's failure to comply with the PMD Act 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 are mainly regulated by Regulations on the Supervision and Administration of Medical Device (Decree No. 739) promulgated by the State Council. National Medical Products Administration (NMPA) is the governmental authority principally responsible for the supervision and administration of medical devices in China.

Each medical device intended for commercial distribution in China is subject to a mandatory filing or registration regime regulated by the NMPA. The classification of such devices mainly determines the filing pathways. China has a three-class classification system, from Class I (lowest risk) to Class III (highest risk). Most of STAAR's medical devices are Class II and Class III devices and are subject to a restricted registration pathway. Applicants are required to submit a product technical requirements (PTR) document, which shall mainly include the performance indicators and testing methods of the medical device. Also, applicants must have samples of the device tested in a government-recognized lab or submit in-house or qualified third-party testing results. The PTR, test reports, quality system documents, labeling information, together with other registration documents, are submitted to the Center for Medical Device Evaluation (CMDE) division of the NMPA for technical evaluation.

If approved, NMPA issues the medical device a registration license valid for five years. The manufacturer submits a renewal application before the license expiration date to renew a medical device's registration.

After approval, in case of substantial changes to the design, raw materials, manufacturing process, and indications, among other things, that may affect the medical device's safety and effectiveness, the manufacturer applies to NMPA for approval of such registration changes. In case of minor changes that do not affect the medical device's safety and effectiveness, the manufacturer submits a change notification to NMPA.

While STAAR Surgical AG and STAAR Surgical Company hold the licenses, STAAR China serves as a local agent. The local agent is authorized to submit the registration application materials to NMPA, and provides maintenance support and technical service, oversees the registration and clinical trial process. Under Decree 1, Medical Device Adverse Event Reporting and Reevaluation, the license holder bears the primary responsibility for monitoring medical device adverse events (AEs), and establishing an AE monitoring system. The local agent helps manage AEsin case of device malfunction.

The license holder and local agent are responsible for carrying out self-inspection of the quality management system periodically. They are also responsible for identifying, monitoring, and trending adverse events related to the medical device.

In Korea, a registration of medical devices such as our ICLs and IOLs is overseen by the Ministry of Food and Drug Safety (MFDS) pursuant to the Medical Device Act. The Medical Device Safety Bureau of the MFDS holds primary responsibility for medical device regulations, while departments within the National Institute of Food and Drug Safety (NIFDS) Evaluation oversee the evaluation and research of medical devices. Medical devices require registration and/or approval prior to commercialization. In Korea, medical device classification closely follows the Global Harmonization Task Force (GHTF) Classification guidelines, with Class I, II, III and IV designation ranked from low to high risk categorization. The registration review route depends on the risk classification of the device. 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 obtains such registrations. In addition to the device registration, MFDS requires all devices Class II and above to comply with Korean Good Manufacturing Practice (KGMP) quality system standards in order to be marketed in Korea. KGMP standards are based on ISO 13485 quality system standards. However, they are not identical. Therefore, ISO 13485 certificates issued by a notified body in the EU will not be sufficient. To obtain KGMP certification, documents that pertain to all areas of compliance, including design, risk assessment, technical requirements and any other quality system requirements, need to be submitted to an MFDS-authorized third party. Our distributor in Korea submits the application on behalf of STAAR. After the application is submitted, the manufacturing site undergoes either a paper audit or an onsite inspection/audit by an authorized third party and MFDS. Medical device registration licenses do not expire, but the KGPM certificate must be renewed every three years.

If the NMPA 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 cataract IOL products used in cataract procedures generally are covered by third-party payers 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.

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 cataract IOLs or our ability to sell these products at prices we consider adequate.

Research and Development

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

During 2022, we intend to continue our focus on research and development in the following areas:

- Development of presbyopia-correcting ophthalmic medical devices, including models that correct cylinder (i.e., astigmatism), including clinical trials of the same;
- Development of preloaded injector systems for ophthalmic medical devices; and
- Development of a new generation of ophthalmic medical devices 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.

Human Capital

Our goal is to develop, manufacture and sell ophthalmic products throughout the world as primary and premium solutions for patients seeking visual freedom from wearing eyeglasses or contact lenses while achieving excellent visual acuity through refractive vision correction. To achieve our goal, we continually seek to attract, develop and retain talented people. We strive to make STAAR a diverse, inclusive, safe workplace, with opportunities for employees to grow and develop their careers. We offer competitive compensation and benefits.

As of December 31, 2021, we had approximately 806 employees, of which 278 were employed outside the U.S. Of the 806 employees, 692 were regular full-time, 9 were regular part-time and 105 were temporary. In fiscal year 2021, we added approximately 206 employees (including temporary employees) to help keep pace with the growth of our business. Our U.S. overall turnover rate in fiscal year 2021 was approximately 9% (excluding temporary employees), below the overall turnover rate of approximately 17% in the medical device industry. We seek employees who reflect the communities where we conduct operations. In the U.S., currently approximately 50% of our employees are female and approximately 50% are male. The gender ratio for our employees globally is approximately 48% female and 52% male. In the U.S., currently approximately 81% of our employees are from underrepresented populations. In 2021, we formalized a global ESG Steering Committee consisting of cross-functional employees to address environmental, social, and governance issue at STAAR. Among our Board of Directors, three directors are female and four directors are male. Two of the directors on our Board of Directors self-identify as members of underrepresented populations.

The health and safety of our employees is a top priority. We created and follow various safety policies and procedures. Also, we offer health insurance and wellness programs. In response to the COVID-19 pandemic, we implemented numerous changes that we determined were in the best interest of our employees and other stakeholders, and which followed guidelines and regulations of the applicable health authorities. For example, the majority of our employees continue to work from home. We implemented additional safety measures for employees who continue critical on-site work such as health screening, implemented social distancing and personal protective equipment requirements, enhanced cleaning and sanitation procedures, and modified workspaces and break areas to reduce the potential for disease transmission.

We invest in our employees by offering numerous training opportunities, such as to teach new skills, provide career development opportunities and communicate expectations regarding business conduct and ethics. In addition to salaries, we provide additional compensation and benefits programs (which vary by country) such as cash bonuses, stock awards, a 401(k) plan, health insurance benefits, health savings and flexible spending accounts, paid time off, family leave, and employee assistance programs, among others.

Code of Ethics

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

Additional Information

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

The SEC maintains an Internet site that contains reports, proxy and information statements, and other information regarding STAAR and other issuers that file electronically with the SEC at http://www.sec.gov.

Glossary

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

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

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

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

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

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

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

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

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

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

intraocular – within the eye.

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

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

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

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

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

ophthalmic – of or related to the eye.

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

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

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

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

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

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

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

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

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

spheric lenses – a spheric lens has surfaces that are shaped like sections of a sphere.

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

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

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

ITEM 1A. Risk Factors

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

Risks Related to Our Business

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

In 2021 our revenue grew by 41% and we achieved $0.50 diluted earnings per share. While we plan to continue sales growth and remain profitable, there can be no guarantee that we will achieve our growth and profitability plans in 2022. While we achieved profitability in the past four consecutive years, we reported losses in three of the past seven years. Our profitability is challenged by the competitive nature of our industry and the other risks to our business detailed herein.

Compliance issues may adversely impact our operations.

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

We rely and depend on independent distributors in international markets.

Except for Japan, Germany, Spain, the U.S., Canada, the U.K. and Singapore, we sell our products through independent distributors who generally control the importation and marketing of our product within their territories. We generally grant exclusive rights to these distributors and rely on them to understand local market conditions, to diligently sell our products and to comply with local laws and regulations. Our agreements with distributors and local laws can make it difficult for us to quickly change from a distributor who we feel is underperforming. If we do terminate an independent distributor, we may lose customers who have been dealing with that distributor, and may be required to compensate the distributor for termination. Because these distributors are independent, it may be difficult for us to detect failures in our distributors' performance or compliance. Actions by independent distributors could result in declining sales in that territory, harm to the reputation of our company or our products, or legal liability. For example, if Shanghai Lansheng, which accounted for approximately 47% of our fiscal 2021 consolidated net sales, ceased to serve as our distributor, or significantly underperformed our expectations, we may experience a substantial reduction in sales.

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

Approximately ninety-two percent (92%) of our revenue was derived from ICL lenses used in refractive procedures. Refractive surgery is an elective procedure generally not covered by health insurance. Patients must pay for the procedure, frequently through installment financing arrangements with third parties. They can defer the choice to have refractive surgery if they lack the disposable income to pay for it or do not feel their income is secure. Economic stagnation, lack of consumer confidence or a recession 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, including our ICL.

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

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

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

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

Further, any failure by us to forecast demand for or to maintain an adequate supply of, raw material and finished product could result in an interruption in the supply of certain products and a decline in the sales of that product. For example, in 2021 our ICL sales grew 51% and orders outstripped our ability to supply. If our suppliers or we are unable or our suppliers are unwilling to meet our increased manufacturing requirements, we may not be able to produce enough materials or products in a timely manner, which could cause a decline in our sales.

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

Activities outside the U.S. accounted for approximately 96% of our total sales during 2021. Foreign currency fluctuations could result in volatility of our revenue. The results of operations and the financial position of our Japanese subsidiary are reported in Japanese yen and then translated into U.S. dollars at the applicable exchange rates for inclusion in our consolidated financial statements, exposing us to translation risk. In addition, we are exposed to transaction risk because we incur some of our sales and expenses in currencies other than the U.S. dollar. Our most significant currency exposures are to the Japanese yen, the euro, and the Swiss franc, and the exchange rates between these currencies and the U.S. dollar may fluctuate substantially. We do not actively hedge our exposure to currency rate fluctuations. The strengthening of the U.S. dollar would likely negatively impact our results. We price some of our products in U.S. dollars, and thus changes in exchange rates can make our products more expensive in some offshore markets and reduce our sales. Inflation could also make our products more expensive and increase the credit risks to which we are exposed. Future foreign currency fluctuations could favorably or unfavorably impact and increase the volatility of our revenue, profitability, and stock price.

Economic, social, and political conditions, laws, practices, and local customs vary widely among the countries in which we sell our products. Our operations outside of the U.S. face a number of risks and potential costs, including, enjoying less stringent protection of intellectual property, and facing economic, political, and social uncertainty in some countries, especially in emerging markets. For example, sales in certain Asian and developing markets may result in lower margins and higher exposure to intellectual property infringement or counterfeits. Also, if China, which accounted for approximately 47% of our fiscal 2021 consolidated net sales, experienced a significant economic downturn, we may experience a significant reduction in sales. Further, trade disputes between the United States and its significant trading partners may adversely affect our sales, including as a result of the imposition of tariffs or other barriers or restrictions on trade, or increase our costs. The institution of trade tariffs both globally and between the U.S. and China specifically could negatively impact the overall economic condition in our markets, including China, which could have a negative effect on our sales. In addition, new laws or regulations in China or elsewhere applicable to foreign medical device companies could negatively impact our business. Also, we are exposed to credit and collectability risk on our trade receivables with customers in certain international markets. There can be no assurance we can effectively limit our credit risk and avoid losses and our ability to transfer foreign earnings to the U.S. may be subject to taxes or restricted or result in incurring substantial costs. Our continued success as a global company depends, in part, on our ability to develop and implement policies and strategies that are effective in anticipating and managing these and other risks in the countries where we do business. These and other risks may have a material adverse effect on our operations in any particular country and on our business, financial condition and results of operations as a whole.

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

We have accumulated approximately $194.7 million of U.S. federal tax net operating loss carryforwards as of December 31, 2021, which can be used to offset taxable income in future years if our U.S. operations become profitable. If unused, the pre-2018 tax loss carryforwards will begin to expire between 2022 and 2037. The enacted legislation commonly known as the Tax Cuts and Jobs Act of 2017, or the Tax Act, subjects a U.S. shareholder to tax on Global Intangible Low Tax Income (GILTI) earned by certain foreign subsidiaries. At this time, our U.S. operations are not profitable, however, recognizing GILTI may offset federal net operating loss carryforwards, as it did for fiscal years 2018 and 2019. Our ability to utilize any future net operating losses may also be limited by the Tax Act. Under the Tax Act, the amount of post-2017 net operating losses we are permitted to deduct in any taxable year is limited to 80% of our taxable income in such year. The unused net operating losses, pre-2018 tax year can still offset 100% of taxable income. In addition, the Tax Act generally eliminates the ability to carry back any net operating loss to prior taxable years, while allowing post-2017 unused net operating losses to be carried forward indefinitely. Due to these changes under the Tax Act, we may not be able to realize a tax benefit from the use of our net operating losses, whether or not we generate profits in future years. Moreover, if we were to experience a significant change in ownership, Internal Revenue Code Section 382 may restrict the future utilization of our tax loss carryforwards even if our U.S. operations generate significant profits.

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

We manufacture most of our products at a single facility in Monrovia, California. All or a portion of the Monrovia facility could suffer catastrophic loss due to fire, flood, earthquake, terrorism or other natural or man-made disasters, including manufacturing challenges such as equipment failure. Developing additional manufacturing sites may require significant expense for personnel and equipment and a long period to obtain regulatory approvals. Our California and Japanese facilities are in areas where earthquakes could cause catastrophic loss.

In our major markets, regulatory approval to manufacture materials and sell our products is generally limited to the current manufacturing site, and changing the site requires applications to and approval from regulatory bodies prior to commercialization. To satisfy our own quality standards as well as regulations, we must follow strict protocols to confirm that products and materials made at a new site are equivalent to those made at the currently approved site. For example, we have commenced activities to resume manufacturing ICLs at our Swiss facility, and to commence manufacturing EVO *Viva* at our Lake Forest facility, but there can be no guaranty whether or when these facilities will be prepared and approved by regulators for manufacturing. Even minor changes in equipment, supplies or processes require validation. Unanticipated delays with a transferred process or difficulties in manufacturing a transferred material could interrupt our supply of products. Any sustained interruption in supply could cause us to lose market share and harm our business, financial condition and results of operations.

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

Public health crises, political crises, and other catastrophic events or other events outside of our control may impact our business.

In 2021, we generated approximately 96% of our total sales outside the U.S. A natural disaster (such as a climate-related event or otherwise), public health crisis (such as a pandemic or epidemic), political crisis (such as terrorism, war, political instability or other conflict), or other events outside of our control that may occur anywhere around the world, may adversely impact our business and operating results. Moreover, these types of events could negatively impact surgeon or patient spending in the impacted region(s) or depending upon the severity, globally, which could adversely impact our operating results.

For example, on March 11, 2020, the World Health Organization ("WHO") characterized the Novel Coronavirus Disease 2019 ("COVID-19") as a pandemic, resulting in governmental authorities and other third parties implementing or recommending a number of measures to contain the spread of COVID-19, including travel restrictions, shelter-in-place orders and business limitations and shutdowns. The impact of COVID-19 and these measures implemented or recommended by governmental authorities and other third parties have had a significant impact on many businesses, including ours. For example, we suspended most of our production on March 17, 2020 with the exception of continuation of critical late-staged processes. Moreover, our revenues have been adversely impacted, since the first quarter of 2020 in global geographies characterized as "hot spots" for the COVID-19 virus and its variants as customers in those locations were not able to carry out procedures or were limited in their activities by government regulations intended to contain the spread of COVID-19 and variant strains. In certain of these markets, sales paused as elective surgeries were discouraged to support COVID-19 related needs. We expect this decrease in sales in certain geographies, such as parts of Europe and Asia, to continue through the first half of 2022 and possibly beyond as different geographies may or may not resume pre-pandemic levels of business activities as novel COVID-19 variant strains emerge. We cannot predict when different governments and circumstances will permit businesses in their jurisdictions to return to pre-pandemic levels of business or when consumers will resume scheduling procedures. We also cannot predict COVID-19's impact on the overall economy of various markets, including the existence or extent of a possible recession. Thus, at this point, the extent to which the coronavirus may impact delayed medical procedures and delayed lens orders, and the related impact on our results is uncertain; however, it could have a material adverse impact on our results of operations, cash flows and financial condition. We monitor such events and take actions that we deem reasonable given the circumstances. In the future other types of crises, may create an environment of business uncertainty around the world, which may hinder sales and/or supplies of our products nationally and internationally.

The extent to which the pandemic impacts our business, operations, and financial results, including the duration and magnitude of such effects, will depend on numerous evolving factors that are uncertain and cannot be predicted, including the following: the duration and scope of the pandemic; the impact it has on global and regional economies and economic activity, including the duration and magnitude of its impact on consumer spending; how quickly and to what extent more customary economic and operating conditions can resume; its impact on our customers' facilities; levels of consumer confidence; whether our COVID-19 preventative measures such as remote working arrangements, changes to manufacturing work areas, such as adherence to social distancing guidelines, and other workforce changes will impact operational efficiency or inventory levels; our ability to obtain supplies from vendors or transport products to customers; or adverse impacts to any other element of our supply chain; the impact on regulatory agencies, including the review and approval process; the impact on clinical studies; the ability of our customers to successfully navigate the impacts of the pandemic such as resuming activities and growing patient interest in our lenses; and actions governments, businesses and individuals take in response to the pandemic.

In addition, the pandemic could adversely impact our ability to recruit and/or retain employees and the continued service and availability of skilled personnel necessary to run our complex production operations, as well as members of our management team, third-party suppliers, distributors and vendors. To the extent our management or other personnel are impacted in significant numbers by the pandemic and are not available to perform their job duties (for example, for health and safety reasons), we could experience delays in, or the suspension of, our manufacturing operations, research and product development activities, regulatory work streams, and other important commercial and operational functions.

Finally, if COVID-19, or a variant strain, continues to spread and escalate domestically or internationally, or if governments impose additional measures intended to mitigate the spread and related effects of the pandemic, the risks described above could be elevated significantly. Should that occur, and the COVID-19 pandemic persist for a prolonged time, the above factors and others that are currently unknown could have a material adverse impact on our business, results of operations, financial conditions and prospects and could elevate known risks described in this Item 1A. Risk Factors.

We depend on key employees.

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

We compete with much larger companies and low-cost Asian manufacturers.

Our primary competitors, including Alcon (formally Novartis), Johnson & Johnson (formerly Abbott Medical Optics, or AMO), Bausch Health Companies (formerly Valeant or Bausch & Lomb), and Carl Zeiss Meditec have much greater financial, technical, marketing and distribution resources and brand name recognition than we do and some of them have large international markets for a full suite of ophthalmic products. Their greater resources for research, development and marketing, and their greater capacity to offer comprehensive products and equipment to providers, makes for intense competition. Over the past several years, we have lost market share in IOL sales to some of our competitors. In addition, competitors from Asia are beginning to appear in some markets with their low-cost version of an implantable contact lens, which competes with our ICL. With our increased commercial success with the ICL, additional companies may seek to enter the refractive phakic intraocular lens market.

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

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

We could experience losses due to product liability claims.

We have been subject to product liability claims in the past and may experience such claims in the future. Product liability claims against us may not be covered, may exceed the coverage limits of our insurance policies or cause us to record a loss in excess of our deductible. A product liability claim that exceeds our insurance coverage could materially harm our business, financial condition, and results of operations. Even if an insurance policy covers a product liability loss, we must generally pay for losses until they reach the level of the policy's stated deductible or retention amount after which the insurer begins paying. The payment of retentions or deductibles for a significant number of claims could have a material adverse effect on our business, financial condition, and results of operations.

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

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

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

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

Our pension plans taken together are underfunded by approximately $8.8 million ($1.3 million for the Japan Plan and $7.5 million for the Swiss Plan) as of December 31, 2021.

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

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

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

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

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

Certain of our employees, contractors and vendors have access to and use personal information in the ordinary course of our business. The secure processing, maintenance and transmission of this information is critical to our operations. Despite our security measures and business controls, our information technology and infrastructure may be vulnerable to attacks by hackers, breaches due to employee, contractor or vendor error, or malfeasance, systems error (whether as a result of an intentional breach, a natural disaster or human error) or other disruptions or subject to the inadvertent or intentional unauthorized release of information. Any such occurrence could compromise our networks and the information stored thereon could be accessed, publicly disclosed, lost or stolen. Any such access, disclosure or other loss of information could result in legal claims or proceedings, and liability under laws that

protect the privacy of personal information and regulatory penalties, disrupt our operations and the supply of products we provide to our clients, compromise our intellectual property or other confidential business information, or damage our reputation, any of which could adversely affect our profitability, revenue and competitive position. Due to the COVID-19 pandemic, we have enabled many of our employees to work remotely, which may make us more vulnerable to cyberattacks. While we have not experienced a material system failure, accident or security breach to date, we cannot assure you that our data protection efforts and our investment in information technology will prevent significant breakdowns, data leakages, breaches in our systems or other cyber incidents that could have a material adverse effect upon our reputation, business, operations or financial condition. We continue to invest in our cybersecurity program to enhance current capabilities and also implementation new capabilities in our effort to keep pace with the changing threat landscape. 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 materially harm our reputation and financial results. Moreover, while we maintain cyber insurance, it may be insufficient to address any potential loss incurred. We also rely on third parties to host or otherwise process some of this data (such as cloud-based computing). Elements of our information technology systems that we outsource to third parties may also be vulnerable to various types of attacks or disruptions. Any failure by a third party to prevent security breaches could have adverse consequences for us.

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

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

New technologies are increasingly used to communicate about our products and the health conditions they are intended to treat. The use of these media poses risks to our business and requires specific attention and monitoring. For example, patients, competitors, or others may use these channels to comment on the safety or effectiveness of a product and to report an alleged adverse event. Negative posts or comments about us or our business on any social networking web site could harm our reputation. In addition, our employees may use social media tools and mobile technologies inappropriately, which may give rise to liability, or which could lead to the exposure of sensitive information. In either case, such uses of social media and mobile technologies could have a material adverse effect on our business, financial condition, and results of operations.

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

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

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

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

If we continue to experience rapid growth, this places a significant strain on financial, operational, and managerial resources. We must continue to implement and enhance our managerial, operational and financial systems, expand our operations, and continue to recruit and train qualified personnel. There can be no assurance that our strategic and operational planning will allow us to adequately manage anticipated growth. Factors such as a failure to follow specific internal practices and procedures, equipment malfunction, environmental factors or damage

to one or more of our facilities could adversely affect our ability to manufacture our products. For example, in the second half of 2021, as we increased production to meet increased demand, we experienced a decline in product yield. In the event of a slower-than-planned manufacturing output, we may be unable to quickly meet customer demand. In the event of a significant manufacturing challenge, we may experience delays in meeting product demand which could adversely affect our results of operations and financial condition

In addition, the expense associated with increased manufacturing and sales/marketing to meet increased demand may exceed our expectations. We manufacture in the U.S. and inflation has increased significantly in the U.S. during recent months, and we can expect as a result to experience increased costs in our own supply chain which may be difficult to pass along to our customers. Any inability to successfully manage growth could materially and adversely affect our business, financial condition, and results of operation.

Corporate responsibility, specifically related to environmental, social and governance ("ESG") matters, may impose additional costs, expose us to reputational and emerging areas of risks, and could negatively affect our business.

Investors, stockholders, customers, suppliers and other third parties are increasingly focusing on ESG and corporate responsibility practices and reporting. Companies that do not adapt to or comply with the evolving investor or stakeholder expectations and standards, as well as the evolving international regulations relating to ESG matters, or which are perceived to have not responded appropriately, may suffer from reputational damage and result in the business, financial condition and/or stock price of a company being materially and adversely affected. Further, this increased focus on ESG issues may result in significant increase in additional expenses (e.g., direct or indirect cost of energy, materials, manufacturing, distribution, packaging and other operating costs) to comply with evolving regulations and/or third-party requirements that could adversely impact our business or profitability.

In response to stakeholder expectations, we have commenced reporting of our sustainability endeavors and future plans. These disclosures reflect our current aspirations and are not guarantees that we will be able to achieve them. Our efforts to accomplish and accurately report on these plans present numerous risks, any of which could have a material negative impact on us. Our ability to achieve any goal, including with respect to ESG-related initiatives, is subject to numerous risks, many of which are outside of our control. Certain shareholders may reduce or eliminate their holdings of our stock based on ESG issues. For example, an allegation or perception that we have not taken sufficient action in these areas could negatively harm our reputation and/or result in certain investors reducing or eliminating their holdings of our stock.

Our method of tracking our ESG efforts may change as expectations and standards evolve, which may result in revisions to our goals or reported progress. If our ESG practices do not meet evolving investor or other stakeholder expectations and standards, then our reputation, and our attractiveness as an investment or business partner could be negatively impacted. Similarly, our failure or perceived failure to pursue or fulfill certain targets or goals, or to satisfy various reporting standards could also have negative impacts and expose us to government enforcement actions and private litigation.

Finally, we expect to incur additional costs and require additional resources to monitor, report, and comply with our various ESG practices. If we fail to adopt ESG standards or practices as quickly as stakeholders desire, report on our ESG efforts or practices accurately, or satisfy the expectations of stakeholders, our reputation, business, financial performance and growth may be adversely impacted.

Climate changes could negatively affect our business.

Climate changes, such as extreme weather conditions, could create financial risk to our business. Global physical climate changes, including unseasonable weather conditions and earthquakes, could disrupt our operations by impacting the availability and cost of materials within our supply chain, and could also increase insurance and other operating costs. This could in turn put pressure on our manufacturing costs and result in reduced profit margin associated with certain of our products.

Risks Related to the Ophthalmic Products Industry

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

Our future growth depends, in part, on our ability to timely develop products to treat diseases and disorders of the eye that are more effective, safer, or incorporate emerging technologies better than our competitors' products, and are accepted by physicians and patients. Sales of our existing products may decline rapidly if one of our

competitors introduces a superior product, or if we announce a new product of our own. If we focus on research and development or technologies that do not lead to better products, more effective or advanced products could surpass our current and planned products. In addition, such product development efforts could require a significant investment of resources. If we are able to develop new products, we must manufacture these products economically and market them successfully by demonstrating to enough eye-care professionals the overall benefits of using them. If we do not timely develop new products that meet market demand or if there is insufficient demand for our new products, our sales and results of operations could be harmed. For example, it is uncertain whether physicians in countries that recognize the CE Mark will adopt the EVO *Viva* lens for use in presbyopic eyes, which our Notified Body approved for marketing and sale in July 2020.

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

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

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

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

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

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

We are regulated by regional, national, state and local agencies in the U.S. as well as governmental authorities in those international countries in which we manufacture or distribute products, such as in Europe and Asia. These regulations may govern the research, development, manufacturing, and commercial activities relating to medical devices, including their design, pre-clinical and clinical testing, clearance or approval, production, labeling, sale, distribution, import, export, post-market surveillance, advertising, dissemination of information and promotion. Failure to receive necessary approvals in foreign jurisdictions on a timely basis, or at all, could harm our business and operating results. In addition, regulations and requirements for approvals can vary in each international country, which can significantly increase the costs to sell our products in these international countries.

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

Competing in the ophthalmic products industry requires us to introduce new or improved products and processes continuously, and to submit these to the FDA and other regulatory bodies for clearance or approval. Obtaining clearance or approval can be a long and expensive process, and clearance or approval is never certain. For example, the FDA or another country's regulatory agency, could require us to conduct an additional clinical trial prior to granting clearance or approval of a product and such clinical trial could take a long time and have substantial expense. Furthermore, there is no assurance that clearance or approval will be granted.

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

In addition, the FDA and other regulatory authorities may change their clearance and approval policies, adopt additional regulations, or revise existing regulations, or take other actions which may prevent or delay approval or clearance of our products under development, cause the loss of previously received approvals or clearances or impact our ability to modify our currently cleared products on a timely basis. Also, we expect to incur additional costs complying with the European Union's new Medical Device Regulation (MDR).

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

While we rely on various intellectual property laws, contractual provisions and confidentiality procedures and copyright laws to protect the proprietary aspects of our technology, we rely more on trade secrets and know-how, which may not prevent third parties from using publicly available information to access our technology. With respect to our patents, any of them may be challenged, invalidated, circumvented or rendered unenforceable. Any of our pending patent applications may fail to result in an issued patent or fail to provide meaningful protection against competitors or competitive technology. Litigation may be necessary to enforce our intellectual property rights, and to protect or determine the validity and scope of our proprietary rights. We also challenge others' patents or patent applications from time to time. Any litigation could result in substantial expense, may reduce our profits, and may not adequately protect our intellectual property rights. In addition, we may be exposed to future litigation by third parties based on claims that our products infringe their intellectual property rights. This risk is exacerbated by the fact that the validity and breadth of claims covered by patents in our industry may involve complex legal issues that are open to dispute. Any litigation or claims against or instituted by us, whether or not successful, could result in substantial costs, divert resources and the efforts of our personnel away from daily operations, harm our reputation, result in the impairment of our intellectual property rights, limit our ability to pursue future products and/or otherwise materially adversely impact our business.

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

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

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

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

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

Our relationships with physicians, and other healthcare providers are subject to scrutiny under various U.S. and international bribery, fraud and abuse, anti-kickback, false claims, privacy, and similar laws, collectively referred to as "healthcare compliance laws." Healthcare compliance laws are broad, sometimes ambiguous, complex, and subject to change and changing interpretations, which could restrict our sales or marketing practices. Possible sanctions for violation of these healthcare compliance laws include fines, civil and criminal penalties, exclusion from government healthcare programs, and despite our compliance efforts, we face the risk of an enforcement activity or a finding of a violation of these laws.

We have entered into a variety of agreements with healthcare professionals. We have also adopted a Code of Business Conduct and Ethics as well as a Compliance Program for Interactions with Healthcare Professionals which govern our relationships with healthcare professionals to bolster our compliance with healthcare compliance laws. While our relationships with healthcare professionals are structured to comply with applicable laws and we provide training on these laws and our Code and Program, it is possible that enforcement authorities may view our relationships as prohibited arrangements that must be restructured or for which we would be subject to other significant civil or criminal penalties or debarment. In any event, any enforcement review of or action against us as a result of such review, regardless of outcome, could be costly and time consuming. Additionally, we cannot predict the impact of any changes in or interpretations of these laws. 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 now or in the future, we may be subject to penalties, including civil and criminal penalties, damages, fines, and disgorgement, any of which could adversely affect our ability to operate our business and our financial results.

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

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

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

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

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

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

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

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

If we modify our products, we may have to obtain new marketing clearances or approvals, or may have to cease marketing or recall the modified products until clearances or approvals are obtained.

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

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

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

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

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

Risks Related to Ownership of Our Common Stock

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

The market price for our common stock has fluctuated widely. The closing price of our common stock ranged from $78.50 to $162.68 per share during the year ended December 31, 2021. Our stock price could continue to experience significant fluctuations in response to factors such as market perceptions, quarterly variations in operating results, operating results that vary from the expectations of securities analysts and investors, changes in financial estimates, changes in the business and market valuations of competitors, announcements by us or our competitors of a material nature, additions or departures of key personnel, future sales of our common stock and stock volume fluctuations. Also, general political and economic conditions such as a recession or interest rate fluctuations, and public health crises, may adversely affect the market price of our common stock.

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

We have not paid any cash dividends on our common stock since our inception. We currently expect to retain any earnings for use to further develop our business, and do not expect to declare cash dividends on our common stock in the foreseeable future. The declaration and payment of any such dividends in the future depends upon our earnings, financial condition, capital needs, and other factors deemed relevant by our Board of Directors, and may be restricted by future agreements with lenders. As a result, the success of an investment in our common stock will depend entirely upon any future appreciation. There is no guarantee that our common stock will appreciate in value or even maintain the price at which stockholders purchase their shares.

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

- stockholders cannot act by consent;
- stockholders cannot fill vacancies on our Board of Directors;
- certain provisions, including those related to changing the number of directors, limiting our stockholders' ability to fill vacancies on our Board of Directors, prohibiting stockholder action by written consent, and amending such provisions, cannot be altered, amended or repealed, and provisions inconsistent therewith cannot be adopted, without the affirmative vote of holders of at least two-thirds in voting power of our outstanding shares of common stock entitled to vote thereon; and
- stockholders must give advance notice to nominate directors or propose other business.

In addition, we are generally subject to the anti-takeover provisions of Section 203 of the Delaware General Corporation Law, which regulates corporate acquisitions. These provisions could discourage potential acquisition proposals and could delay or prevent a change in control transaction. They could also have the effect of discouraging tender offers for our common stock or prevent changes in our management.

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

Our largest investor beneficially owns approximately 18% of our outstanding common stock, and our largest four investors beneficially own approximately 50% of our outstanding common stock. Two of our current seven directors were recommended by our investors. The sale of a substantial number of shares of our common stock by any or all of our largest investors or our other stockholders within a short period of time could cause our common stock price to decline, make it more difficult for us to raise funds through future offerings of our common stock or acquire other businesses using our common stock as consideration.

In addition, having such a concentration of ownership may have the effect of making it more difficult for a third party to acquire, or of discouraging a third party from seeking to acquire, a majority of our outstanding common stock or control of our Board of Directors, including through a proxy solicitation.

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

We could issue additional shares of common or preferred stock to raise additional capital or for other corporate purposes without stockholder approval. In addition, we could designate and sell a class of preferred stock with preferential rights over our common stock with respect to dividends or other distributions. Also, we have filed a universal shelf registration statement with the Securities and Exchange Commission. The shelf registration statement is available to cover the future public offering and sale of up to approximately $200,000,000 in equity or debt securities or any combination of such securities. Sales of our common or preferred stock under the shelf registration or in other transactions could dilute the interest of existing stockholders and reduce the market price of our common stock. Even in the absence of such sales, the perception among investors that additional sales of equity securities may take place could reduce the market price of our common stock.

ITEM 1B. Unresolved Staff Comments

None.

ITEM 2. Properties

Our operations are conducted in leased facilities throughout the world. Our global administrative offices, principal manufacturing, warehouse and distribution, are in Monrovia, California. STAAR Surgical AG maintains administrative offices, manufacturing capabilities, warehouse and distribution facilities in Nidau and Brügg, Switzerland. Our facility in Lake Forest, California serves as our corporate headquarters and is expected to handle manufacturing of the EVO *Viva* to correct or reduce presbyopia after the facility's approval. The Company leases a research and development facility in Tustin, California and a facility in Aliso Viejo, California for raw material production and research and development activities. STAAR Japan maintains executive offices in Shin-Urayasu, Japan and a final packaging and inspection and distribution facility in Ichikawa City, Japan. We believe our operating facilities in the U.S., Switzerland and Japan are suitable and adequate for our current requirements. The Company could increase capacity as needed.

ITEM 3. Legal Proceedings

Certain of the legal proceedings in which we are involved are discussed under "Litigation and Claims" in Note 13, "Commitments and Contingencies," to our Consolidated Financial Statements in this Annual Report on Form 10-K, and are hereby incorporated by reference.

ITEM 4. Mine Safety Disclosures

None.

PART II

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

Market Information

Our common stock is traded on the Nasdaq Global Market (NASDAQ) under the symbol "STAA."

Holders

As of February 18, 2022, there were approximately 288 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

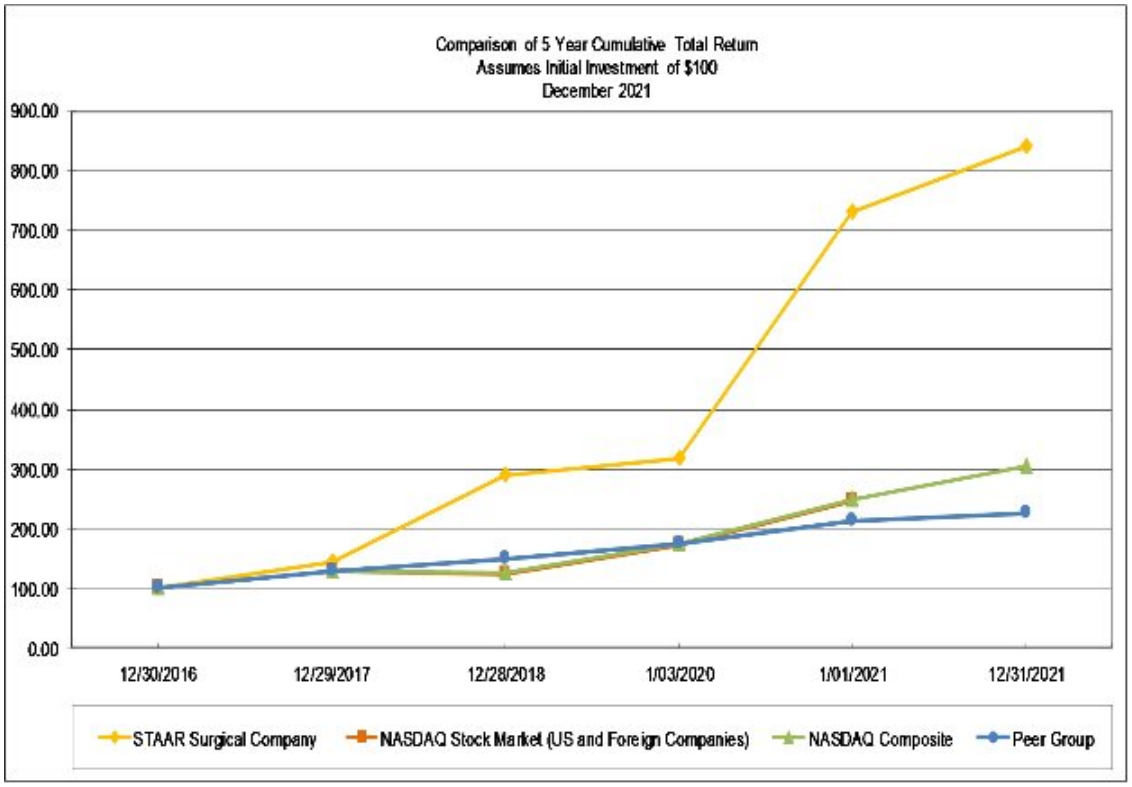
This performance graph shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the Exchange Act), or incorporated by reference into any filing of STAAR Surgical Company under the Securities Act of 1933, as amended, or the Exchange Act, except as shall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

The following graph shows a comparison from December 30, 2016 to December 31, 2021 of the total performance of the following:

- STAAR Surgical Company;
- The NASDAQ Composite Index replaces the CRSP NASDAQ Stock Market (US and Foreign Companies) Index in this analysis and going forward, as the CRSP Index data is no longer accessible. The CRSP index has been included with data through 2020;
- a peer group we have selected based on data and advice provided by the Radford Group, consisting of the following 16 companies:

Angio Dynamics (ANGO)	Inogen (INGN)
Anika Therapeutics (ANIK)	LeMaitre Vascular (LMAT)
AtriCure (ATRC)	Merit Medical Systems (MMSI)
Atrion (ATRI)	Nevro (NVRO)
AxoGen (AXGN)	Penumbra (PEN)
Cardiovascular Systems (CSII)	Surmodics (SRDX)
CryoLife (CRY)	Tactile Systems Technology (TCMD)
Glaukos (GKOS)	Tandem Diabetes Care (TNDM)

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, 2016 in STAAR common stock and in each of the composite indices, and that dividends (if any) were reinvested. We have never paid dividends on our common stock and have no present plans to do so.



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Total Returns Index for Fiscal Years:	2016	2017	2018	2019	2020	2021
STAAR Surgical Company	100.00	142.86	288.12	316.87	730.15	841.49
The Nasdaq Stock Market (US and Foreign Companies)	100.00	129.37	124.60	171.38	244.69	—
The Nasdaq Composite Index	100.00	129.64	124.98	173.12	249.51	304.85
Peer Group	100.00	128.58	149.79	174.19	211.96	226.23

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 December 30, 2016.

ITEM 6. [Reserved]

ITEM 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

The matters addressed in this Item 7 that are not historical information constitute "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Readers can recognize forward-looking statements by the use of words like "anticipate," "estimate," "expect," "intend," "plan," "believe," "will," "should," "forecast" and similar expressions in connection with any discussion of future operating or financial performance. In particular, these include statements about any of the following: any guidance as to earnings, revenue, sales, profit margins, expense rate, cash, effective tax rate, product mix, capital expense or any other financial items; the expected impact of the COVID-19 pandemic and related public health measures (including but not limited to their impact on sales, operations or clinical trials globally), the plans, strategies, and objectives of management for future operations or prospects for achieving such plans; statements regarding new, existing, or improved products, including but not limited to, expectations for success of new, existing, and improved products in the U.S. or international markets or

government approval of a new or improved products (including the EVO family of lenses in the U.S. and the EVO Viva family of lenses for presbyopia internationally); commercialization of new or improved products; future economic conditions or size of market opportunities; expected costs of operations; statements of belief, including as to achieving 2022 business plans; expected regulatory activities and approvals, product launches, and any statements of assumptions underlying any of the foregoing.

Although we believe that the expectations reflected in these forward-looking statements are reasonable, such statements are inherently subject to risks and we can give no assurance that our expectations will prove to be correct. Actual results could differ from those described in this report because of numerous factors, many of which are beyond our control. These factors include, without limitation, those described in this Annual Report in "Item 1A. Risk Factors." We undertake no obligation to update these forward-looking statements after the date of this report to reflect future events or circumstances or to reflect actual outcomes.

The following discussion should be read in conjunction with the audited consolidated financial statements of STAAR, including the related notes, provided in this report.

Overview

STAAR Surgical Company designs, develops, manufactures, and sells implantable lenses for the eye and companion delivery systems used to deliver the lenses into the eye. We are the world's leading manufacturer of intraocular lenses for patients seeking lens-based refractive vision correction, and we also make lenses for use in surgery to treat cataracts. All the lenses we make are foldable, which allows the surgeon to insert them into the eye through a small incision during minimally invasive surgery. Refractive surgery is performed to treat the type of visual disorders that have traditionally been corrected using eyeglasses or contact lenses. We refer to our lenses used in refractive surgery as "implantable Collamer® lenses" or "ICLs." The field of refractive surgery includes both lens-based procedures, using products like our ICL family of products, and laser-based procedures like LASIK. Successful refractive surgery can correct common vision disorders such as myopia, hyperopia, and astigmatism. Cataract surgery is a common outpatient procedure where the eye's natural lens that has become cloudy with age is removed and replaced with an artificial lens called an intraocular lens (IOL) to restore the patient's vision. STAAR employs a commercialization strategy that strives for increased share of the refractive market and sustainable profitable growth. Our goal is to position our refractive lenses throughout the world as primary and premium solutions for patients seeking visual freedom from wearing eyeglasses or contact lenses while achieving excellent visual acuity through refractive vision correction. We position our IOL lenses used in surgery that treats cataracts based on quality and value.

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

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

Strategic Imperatives for 2022

For 2022 we intend to achieve the following strategic imperatives:

- Position EVO Implantable Lenses as a Special and Transformational Pathway to *Visual Freedom*;
- Innovate and Develop a Pipeline of Next Generation Premium Collamer-Based Intraocular Lenses;
- Support the Transformation of the Refractive Surgery Paradigm to Lens-Based through Clinical Validation and Medical Affairs Excellence;
- Achieve our corporate imperatives in alignment with our Environmental, Social and Governance commitments;
- Continue our Focus on and Commitment to STAAR's *Culture of Quality*; and
- Deliver Shareholder Value.

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

We continue to monitor the commercial and operational impact of new variants of COVID-19 in our markets, which remains uncertain at this time and may adversely affect our financial results. For example, COVID-19 impacted certain of our European customers and, in the U.S., STAAR's manufacturing operations. Production output and modest supply chain challenges continue to impact us and resulted in a continued backlog of over 20,000 lenses at the end of the fourth quarter. We continue to focus on meeting the significant demand of our ICL lenses and achieving standard inventory level requirements in 2022.

Results of Operations

The following table sets forth the percentage of total sales represented by certain items reflected in the Company's Consolidated Statement of Income for the period indicated.

	Percentage of Net Sales		
	2021	**2020**	**2019**
Net sales	100.0%	100.0%	100.0%
Cost of sales	22.5%	27.6%	25.5%
Gross profit	77.5%	72.4%	74.5%
General and administrative	19.1%	20.7%	19.5%
Selling and marketing	29.2%	28.0%	30.3%
Research and development	14.7%	19.6%	16.8%
Total selling, general and administrative	63.0%	68.3%	66.6%
Operating income	14.5%	4.1%	7.9%
Total other income (expense), net	(0.9)%	0.9%	0.8%
Income before income taxes	13.6%	5.0%	8.7%
Provision (benefit) for income taxes	3.0%	1.4%	(0.7)%
Net income	10.6%	3.6%	9.4%

Net Sales

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

	2021		**2020**		**2019**	
	% of Total	**Sales**	**% of Total**	**Sales**	**% of Total**	**Sales**
ICLs	92.4%	$ 212,905	86.5%	$ 141,407	86.1%	$ 129,322
Other product sales						
Cataract IOLs	5.4%	12,519	8.3%	13,574	10.5%	15,689
Other surgical products	2.2%	5,048	5.2%	8,479	3.4%	5,174
Total other product sales	7.6%	17,567	13.5%	22,053	13.9%	20,863
Net sales	100.0%	$ 230,472	100.0%	$ 163,460	100.0%	$ 150,185

Net sales for 2021 increased 41% from 2020. The increase in net sales was due to increased ICL sales of $71.5 million, partially offset by a decrease in other product sales of $4.5 million. Changes in foreign currency favorably impacted net sales by $0.5 million.

Net sales for 2020 increased 9% from 2019. The increase in net sales was due to increased ICL sales of $12.1 million and in other product sales of $1.2 million. Changes in foreign currency favorably impacted net sales by $1.5 million.

Total ICL sales for 2021 increased 51% from 2020, with unit growth up 48%. The sales increase was driven by the APAC region, which grew 51% with unit growth of 47%, primarily due to sales growth in India up 123%, Japan up 56%, China up 50%, other APAC Distributors up 50% and Korea up 36%. The Europe, Middle East, Africa and Latin America region sales increased 46% with unit increase of 48%, due to sales growth in the Middle East and North Africa up 81%, Latin America up 68%, United Kingdom up 61%, Distributor Operations up 45%, Spain up 40% and Germany up 35%. The North America region sales increased 57%, with unit increase of 61%, due to sales growth in the U.S. up 58% and Canada up 53%. Changes in foreign currency favorably impacted ICL sales by $0.8 million. ICL sales represented 92.4% of our total sales for fiscal year 2021.

Total ICL sales for 2020 increased 9% from 2019, with unit growth up 11%. The sales increase was driven by the APAC region, which grew 15% with unit growth of 17%, primarily due to sales growth in Japan up 56%, other APAC Distributors up 38%, Korea up 17% and China up 11%. The Europe, Middle East, Africa and Latin America region sales decreased 3% and units decreased 11%, as a result of decreased sales in the Middle East and North Africa down 35%, Latin America down 13% and Spain down 4%, partially offset by sales growth in Germany up 15%, the United Kingdom up 8% and Other Distributors up 4%. The North America region sales decreased 14% and units decreased 12%, mainly due to decreased sales in the U.S. down 17%, slightly offset by sales growth in Canada up 2%. The decreases in these various regions were impacted by the COVID-19 pandemic in the first half of 2020; most markets started to reopen in mid-May/early June, with India and the Middle East being the two markets that remained the most challenged by COVID-19 during the second half of 2020. Changes in foreign currency favorably impacted ICL sales by $1.0 million. ICL sales represented 86.5% of our total sales for fiscal year 2020.

Other product sales, including cataract IOLs for 2021 decreased 20% from 2020, mainly due to product yield issues requiring rework related to preloaded injector parts manufactured on our behalf by a third-party manufacturer then sold by us to a third-party manufacturer for product they sell to their customers, as well as decreased cataract IOL sales. Changes in foreign currency unfavorably impacted other product sales by $0.3 million. Other product sales represented 7.6% of our total sales for fiscal year 2021.

Other product sales in 2020 increased 6% from 2019, due to increased preloaded injector part sales to a third-party manufacturer for product they sell to their customers, partially offset by decreased IOL sales. Changes in foreign currency favorably impacted other product sales by $0.5 million. Other product sales represented 13.5% of our total sales for fiscal year 2020.

Gross Profit

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

				Percentage Change	
	2021	**2020**	**2019**	**2021 vs. 2020**	**2020 vs. 2019**
Gross profit	$ 178,637	$ 118,362	$ 111,954	50.9%	5.7%
Gross margin	77.5%	72.4%	74.5%		

Gross profit for 2021 increased 50.9% from 2020. Gross profit margin increased to 77.5% of revenue for 2021 compared to 72.4% of revenue for 2020, due to higher mix of ICL sales, geographic sales mix, a decreased mix of injector part sales which carry a lower margin and the non-recurring expenses related to the 2020 COVID-19 manufacturing pause, partially offset by increased period costs associated with manufacturing expansion projects.

Gross profit for 2020 increased 5.7% from 2019. Gross profit margin decreased to 72.4% of revenue for 2020 compared to 74.5% of revenue for 2019, due to geographic sales mix, $1.2 million in expenses related to the COVID-19 manufacturing pause from March 17 through April 27, 2020, increased period costs associated with the manufacturing expansion projects and increased mix of injector part sales which carry a lower margin, partially offset by increased ICL volume.

General and Administrative Expense

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

				Percentage Change	
	2021	**2020**	**2019**	**2021 vs. 2020**	**2020 vs. 2019**
General and administrative expense	$ 44,142	$ 33,911	$ 29,313	30.2%	15.7%
Percentage of sales	19.1%	20.7%	19.5%		

General and administrative expenses for 2021 increased 30.2% from 2020, due to increased bonus and stock-based compensation expenses, salary-related and payroll tax expenses, outside services, facilities costs and corporate insurance.

General and administrative expenses for 2020 increased 15.7% from 2019, due to increased salary-related and payroll expenses, stock-based compensation expenses, tax consulting, corporate insurance and facility costs, slightly offset by decreased travel expenses.

Selling and Marketing Expense

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

				Percentage Change	
	2021	2020	2019	2021 vs. 2020	2020 vs. 2019
Selling and marketing expenses	$ 67,294	$ 45,764	$ 45,491	47.0%	0.6%
Percentage of sales	29.2%	28.0%	30.3%		

Selling and marketing expenses for 2021 increased 47.0% from 2020, due to increased advertising and promotional activities, salary-related and payroll tax expenses, trade shows expense, commission expense, and bonus and stock-based compensation expenses.

Selling and marketing expenses for 2020 increased 0.6% from 2019, due to increased advertising and promotional activities and salary-related and payroll expenses, offset by decreased trade shows and travel expenses.

Research and Development Expense

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

				Percentage Change	
	2021	2020	2019	2021 vs. 2020	2020 vs. 2019
Research and development expense	$ 33,862	$ 31,918	$ 25,298	6.1%	26.2%
Percentage of sales	14.7%	19.6%	16.8%		

Research and development expenses for 2021 increased 6.1% from 2020 due to increased bonus and stock-based compensation expenses and salary-related and payroll tax expenses, partially offset by decreased clinical expenses associated with our U.S. EVO clinical trial.

Research and development expenses for 2020 increased 26.2% from 2019 primarily due to increased clinical expenses associated with our EVO clinical trial in the U.S., and increased salary-related and payroll tax expenses.

Research and development expense consist primarily of compensation and related costs for personnel responsible for the research and development of new and existing products, the regulatory and clinical activities required to acquire and maintain product approvals globally and medical affairs expenses. These costs are expensed as incurred.

Other Income (Expense), Net

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

				Percentage Change	
	2021	2020	2019	2021 vs. 2020	2020 vs. 2019
Other income (expense), net	$ (2,035)	$ 1,498	$ 1,174	—*	27.6%
Percentage of sales	-0.9%	0.9%	0.8%		

* Denotes change is greater than ±100%.

Other expense, net for 2021 was $2.0 million and other income, net for 2020 and 2019 was $1.5 million and $1.2 million, respectively. The change in 2021 was due primarily to increased foreign exchange losses (primarily euro). The increase for 2020 was mainly due to increased foreign exchange gains (primarily euro), partially offset by decreased net interest income, as a result of lower interest rates.

Other income, net generally relates to interest income earned on cash and cash equivalents, interest expense on notes payable and finance lease obligations, gains or losses on foreign currency transactions, and royalty income. The table below summarizes the year over year changes in other income, net (in thousands):

	Favorable (Unfavorable)	
	2021 vs. 2020	2020 vs. 2019
Interest income (expense), net	$ (276)	$ (750)
Foreign exchange	(3,828)	1,381
Royalty income	575	(111)
Other	(4)	(196)
Net change in other income (expense), net	$ (3,533)	$ 324

Provision (Benefit) for Income Taxes

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

				Percentage Change	
	2021	2020	2019	2021 vs. 2020	2020 vs. 2019
Provision (benefit) for income taxes	$ 6,803	$ 2,354	$ (1,022)	—*	—*

* Denotes change is greater than ±100%.

We recorded income taxes for 2021 due to income tax expense generated from pre-tax profits in our foreign jurisdictions and a recapture of our U.S. valuation allowance of $0.8 million, as a result of increased tax deductions in the projection of taxable income in our valuation assessment. From time to time, we may adjust the projections of taxable income as a result of current conditions. We recorded income taxes for 2020 due to income tax expense generated from pre-tax profits in our foreign jurisdictions and a release of $0.5 million of our U.S. valuation allowance, as a result of increases in foreign income and changes in the usage and release of our deferred tax assets. We recorded an income tax benefit for 2019 due to a release of our U.S. valuation allowances of $3.4 million as a result of positive evidence in U.S. projected future profits, offset by income tax expense generated from pre-tax profits in our foreign jurisdictions. During 2021, 2020 and 2019, there were no unrecognized benefits related to uncertain tax positions taken by us.

All earnings from our subsidiaries are not considered to be permanently reinvested. Beginning 2019, we do not need to accrue withholding taxes on foreign earnings (Note 10 to the Consolidated Financial Statements). During 2021, 2020 and 2019 there were no withholding taxes paid to foreign jurisdictions.

ASC 740 requires that a valuation allowance be established when it is more likely than not that all or a portion of a deferred tax asset may not be realizable. The ultimate realization of deferred tax assets is dependent upon future generation of income during the periods in which temporary differences representing net future deductible amounts become deductible. In evaluating our ability to recover our deferred tax assets, we consider among other things, projected future income, tax planning strategies and all other available evidence in making this assessment. Under the incremental cash tax savings approach (Notes 1 and 10 to the Consolidated Financial Statements), our U.S. cumulative valuation allowance was as follows (in thousands):

	2021	2020
Cumulative federal valuation allowance	$ 43,626	$ 34,681
Cumulative state valuation allowance	7,848	7,399
Total U.S. valuation allowance	$ 51,474	$ 42,080

Under the incremental cash tax savings approach, the U.S. valuation allowance recorded reflects the net operating losses and deferred tax assets which would not result in future cash tax savings and therefore provide no additional benefit. Total U.S. net deferred tax assets were $3.0 million and $3.9 million at December 31, 2021 and January 1, 2021, respectively.

A reconciliation of the federal statutory income tax rate to our effective tax rate is set forth in Note 10 of Notes to the Consolidated Financial Statements included in Item 8 of this Annual Report on Form 10-K.

Liquidity and Capital Resources

We believe that current cash, cash equivalents and future cash flow from operating activities will be sufficient to meet our anticipated cash needs, including working capital needs, capital expenditures and contractual obligations for at least 12 months from the issuance date of the financial statements included in this Annual Report. Our financial condition at December 31, 2021, January 1, 2021 and January 3, 2020 included the following (in millions):

	2021	2020	2019	2021 vs. 2020	2020 vs. 2019
Cash and cash equivalents	$ 199.7	$ 152.5	$ 120.0	$ 47.2	$ 32.5
Current assets	$ 271.4	$ 216.4	$ 174.7	$ 55.0	$ 41.7
Current liabilities	48.8	41.2	34.5	7.6	6.7
Working capital	$ 222.6	$ 175.2	$ 140.2	$ 47.4	$ 35.0

We invest our net proceeds in short-term interest-bearing obligations, investment-grade instruments, certificates of deposit or direct or guaranteed obligations of the U.S. government. Additionally, during 2021 we fully repaid and cancelled our Japan line of credit and cancelled our Swiss framework agreement given our current cash resources. We do not have any off-balance sheet arrangements.

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

A summary of cash flows for the fiscal years presented (dollars in thousands):

	2021	2020	2019
Cash flows from:			
Operating activities	$ 43,962	$ 20,951	$ 25,795
Investing activities	(13,645)	(8,404)	(10,178)
Financing activities	17,793	19,571	149
Effect of exchange rate changes	(857)	367	203
Net increase in cash and cash equivalents	47,253	32,485	15,969
Cash and cash equivalents, at beginning of year	152,453	119,968	103,999
Cash and cash equivalents, at end of year	$ 199,706	$ 152,453	$ 119,968

For 2021, net cash provided by operating activities consisted of $24.5 million in net income and $21.9 million in non-cash items, offset by $2.4 million in working-capital changes. For 2020, net cash provided by operating activities consisted of $17.8 million in non-cash items and $5.9 million in net income, offset by $2.7 million in working-capital changes. For 2019, net cash provided by operating activities consisted of $14.0 million in net income and $13.0 million in non-cash items, offset by $1.2 million in working-capital changes.

The increase in investment in property, plant and equipment during 2021, relative to 2020, is primarily due to an increased in investments in manufacturing facilities. The decrease in investment in property, plant and equipment during 2020, relative to 2019, is primarily due to a slight decrease in investments in manufacturing facilities.

For 2021, net cash provided by financing activities consisted of $19.4 million of proceeds from the exercise of stock options, partially offset by $1.3 million repayment on the Japan line of credit and $0.3 million repayment of finance lease obligations. For 2020, net cash provided by financing activities consisted of $20.6 million of proceeds from the exercise of stock options, partially offset by $0.6 million repayment of finance lease obligations and a $0.5 million repayment on the Japan line of credit. For 2019, net cash provided by financing activities consisted of $3.5 million of proceeds from the exercise of stock options, offset by a $2.0 million repayment on the Japan line of credit and $1.3 million repayment of finance lease obligations.

Accounts receivable, net was $43.5 million and $35.2 million at December 31, 2021 and January 1, 2021, respectively. Days' Sales Outstanding (DSO) was 67 and 70 days, respectively in 2021 and 2020. The decrease in DSO was mainly due to increased customer collections of receivables in the fourth quarter of 2021.

Inventories, net was $17.2 million and $18.1 million at December 31, 2021 and January 1, 2021, respectively. Days' Inventory on Hand (DOH) was 79 and 114 days in 2021 and 2020, respectively, for finished goods, including consignment inventory. The decrease in DOH is due to increased sales of ICL products resulting in more frequent inventory turnover.

Shelf Registration

On May 6, 2020, STAAR filed a universal shelf registration statement with the SEC covering the future public offering and sale of up to $200 million in equity or debt securities or any combination of such securities. The shelf registration statement became effective on February 22, 2021 and expires on February 22, 2024. Among the purposes for which STAAR could use the proceeds of securities sold in the future under the shelf registration statement are working capital, capital expenditures, expansion of sales and marketing, and continuing research and development. STAAR could also use a portion of the net proceeds to acquire or invest in businesses, assets, products, and technologies that are complementary to our own, although we are not currently contemplating or negotiating any such acquisitions or investments. The availability of financing in the public capital markets through the shelf registration statement depends on several factors in place at the time of financing, including the strength of STAAR's business performance, general economic conditions and investment climate, and investor perceptions of those factors. If STAAR seeks financing under the shelf registration statement in the future, we cannot assure that such financing will be available on favorable terms, if at all.

Credit Facilities, Lease Line of Credit, Contractual Obligations, and Commitments

Credit Facilities

Refer to Note 8 to the Consolidated Financial Statements.

Contractual Obligations

The following table represents the Company's known contractual obligations as of December 31, 2021 (in thousands):

	Payments Due by Period				
Contractual Obligations	**Total**	**1 Year**	**2 – 3 Years**	**4 – 5 Years**	**More than 5 Years**
Finance lease obligations (Note 9)*	$ 546	$ 147	$ 357	$ 42	$ —
Operating lease obligations (Note 9)*	36,591	4,993	10,270	7,537	13,791
Pension benefit payments (Note 11)*	8,758	169	484	637	7,468
Severance (Note 13)*	90	90	—	—	—
Asset retirement obligation (Note 13)*	198	—	198	—	—
Open purchase orders (Note 13)*	17,342	16,029	1,250	63	—
Total	$ 63,525	$ 21,428	$ 12,559	$ 8,279	$ 21,259

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

Critical Accounting Estimates

Our accounting policies are more fully described in Note 1 of the Consolidated Financial Statements. As disclosed in Note 1, the preparation of financial statements in accordance with accounting principles generally accepted in the United States of America requires management to make significant estimates and assumptions about future events that affect the amounts reported in the financial statements and accompanying notes. Actual results may differ, significantly at times, from these estimates if actual conditions differ from our assumptions.

We believe the following discussion represents our most critical accounting estimates, which are those that are most important to the portrayal of our financial condition and results of operations and require management's most difficult, subjective and complex judgments.

Sales Return Reserves

We provide allowances for sales returns such that returns are matched against the sales from which they originated. While such allowances have historically been within our expectations, we cannot guarantee that we will continue to experience the same return rates that we have in the past. Measurement of such returns is based on an expected loss model which requires consideration of, among other factors, historical returns experience and current/anticipated trends, including the need to adjust for current conditions and product lines, the entry of a competitor, and judgments about the probable effects of relevant observable data. We consider all available information in our quarterly assessments of the adequacy of the allowance for sales returns.

Allowance for Doubtful Accounts

We maintain provisions for uncollectible accounts based on estimated losses resulting from the inability of our customers to remit payments. While such credit losses have historically been within our expectations and the provisions established, we cannot guarantee that we will continue to experience the same credit loss rates that we have in the past. Measurement of such losses is based on an expected loss model which requires consideration of historical loss experience, including the need to adjust for current conditions, and judgments about the probable effects of relevant observable data, including present economic conditions such as delinquency rates and financial health of specific customers. We consider all available information in our assessments of the adequacy of the reserves for uncollectible accounts.

Stock-Based Compensation

We account for the issuance of stock awards by estimating the fair value of awards issued using the Black-Scholes pricing model. This model's calculations include the exercise price, the market price of shares on grant date, risk-free interest rates, expected term of the award, expected volatility of our stock and expected dividend yield. For those awards which contain a performance condition, stock-based compensation cost will be recognized when it is probable that the performance condition will be achieved, net of an estimate of pre-vesting forfeitures, over the requisite service period based on the grant-date fair value of the stock. We reassess the probability of vesting at each reporting period and adjust stock-based compensation cost based on our probability assessment.

Income Taxes

In evaluating our ability to recover the deferred tax assets within a jurisdiction from which they arise, we consider all available positive and negative evidence, including scheduled reversals of deferred tax liabilities, projected future taxable income, tax-planning strategies, and results of recent operations. In projecting future taxable income, we begin with historical results and incorporate assumptions including overall current and projected business and industry conditions, the amount of future federal, state, and foreign pretax operating income, the reversal of temporary differences and the successful implementation of feasible and prudent tax-planning strategies. These assumptions require significant judgment about the forecasts of future taxable income and are consistent with the plans and estimates management uses to manage its businesses. In evaluating the objective evidence that historical results provide, we also consider three years of cumulative operating results. Valuation allowances, or reductions to deferred tax assets, are recognized if, based on the weight of all the available evidence, it is more likely than not that some portion or all of the deferred tax asset may not be realized.

Inventories

We provide estimated inventory allowances for excess, slow moving, expiring and obsolete inventory as well as inventory whose carrying value is more than net realizable value. These reserves are based on current assessments about future demands, market conditions and related management initiatives. If market conditions and actual demands are less favorable than those projected by management, additional inventory write-downs may be required. We regularly review inventory quantities on hand and record a provision for excess and obsolete inventory based primarily on the expiration of products with a shelf life of less than four months, estimated forecasts of product demand and production requirements for the next twelve months. Several factors may influence the realizability of our inventories, including significant changes in demand, decisions to exit a product line, technological change, and new product development. While such inventory losses have historically been within our expectations and the provisions established, we cannot guarantee that we will continue to experience the same loss rates that we have in the past.

Lease Accounting

We recognize right-of-use (ROU) assets and lease liabilities for leases with terms greater than twelve months. In recording a lease ROU asset, we consider the following lease extensions only if we are reasonably certain to extend the lease. For leases that increase using an inflation rate indicator, we use the inflation rate at the time the lease was entered into for the length of the lease term. In addition, we use our incremental borrowing rate as the discount rate to record the lease ROU asset.

Impairment of Long-Lived Assets

Intangible assets (excluding goodwill) and other long-lived assets (including property, plant and equipment and lease ROU assets) are reviewed for impairment whenever events such as product discontinuance, plant closures, product dispositions or other changes in circumstances indicate that the carrying amount may not be recoverable. Certain factors which may occur and indicate that an impairment exists include, but are not limited to, the following: significant underperformance relative to expected historical or projected future operating results; significant changes in the manner of use of the underlying assets; and significant adverse industry or market economic trends. In reviewing for impairment, we compare the carrying value of such assets to the estimated undiscounted future net cash flows expected from the use of the assets and their eventual disposition. If the carrying value of assets is determined to be unrecoverable, we would estimate the fair value of the assets and record an impairment charge for the excess of the carrying value over the fair value. The estimate of fair value requires management to make several assumptions and projections, which could include, but would not be limited to, future revenues, earnings and the probability of certain outcomes and scenarios.

Employee Defined Benefit Plans - Pension

The liabilities and annual income or expense of our pension plans are determined using methodologies that involve several actuarial assumptions, the most significant of which are the discount rate, expected years of service, salary increases and the expected long-term rate of asset return. The fair values of plan assets are determined based on prevailing market prices.

Foreign Exchange

Management does not believe that the fluctuation in the value of the dollar in relation to the currencies of its suppliers or customers in the last three fiscal years has adversely affected our ability to purchase or sell products at agreed upon prices. No assurance can be given, however, that adverse currency exchange rate fluctuations will not occur in the future, which could significantly affect our operating results. We do not currently hedge transactions to offset changes in foreign currency.

Inflation

Management believes inflation has not had a significant impact on our net sales and revenues and on income from continuing operations during the past three years.

Recent Accounting Pronouncements

See "*Part II. Item 8. "Financial Statements and Supplementary Data – Note 1 – Organization and Description of Business and Accounting Policies – Income Taxes*" of this Annual Report on Form 10-K.

ITEM 7A. Quantitative and Qualitative Disclosures About Market Risk

In the normal course of business, our operations are exposed to risks associated with fluctuations in interest rates and foreign currency exchange rates. The Company manages its risks based on management's judgment of the appropriate trade-off between risks, opportunity, and costs and does not generally enter into interest rate or foreign exchange rate hedge instruments.

Foreign currency risk

Fluctuations in the rate of exchange between the U.S. dollar and foreign currencies in which we transact business could adversely affect our financial results.

Our international subsidiaries operate in and are net recipients of currencies other than the U.S. dollar and, as a result, our sales benefit from a weaker dollar and are reduced by a stronger dollar relative to major currencies worldwide (primarily, the euro and the Japanese yen). Accordingly, changes in exchange rates, and particularly the strengthening of the U.S. dollar, may negatively affect our consolidated sales and gross profit as expressed in U.S. dollars. Fluctuations during any given reporting period result in the re-measurement of our foreign currency denominated cash, receivables, and payables, generating currency transaction gains or losses and are reported in total other income (expense), net in our Consolidated Statements of Income. In the normal course of business, we also face risks that are either non-financial or non-quantifiable. Such risks include those set forth in "*Item 1A. Risk Factors*."

ITEM 8. Financial Statements and Supplementary Data

Financial Statements and the Report of Independent Registered Public Accounting Firm are filed with this Annual Report on Form 10-K in a separate section following Part IV, as shown on the index under Item 15 of this Annual Report.

ITEM 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

ITEM 9A. Controls and Procedures

Attached as exhibits to this Annual Report on Form 10-K are certifications of STAAR's Chief Executive Officer (CEO) and Chief Financial Officer (CFO), which are required in accordance with Rule 13a-14 of the Securities Exchange Act of 1934, as amended (the Exchange Act). This "Controls and Procedures" section includes information concerning the controls and controls evaluation referred to in the certifications. The report of BDO USA, LLP, our independent registered public accounting firm, regarding its audit of STAAR's internal control over financial reporting follows below. This section should be read in conjunction with the certifications and the BDO USA, LLP report for a more complete understanding of the topics presented.

Evaluation of Disclosure Controls and Procedures

As of the end of the period covered by this report, we carried out an evaluation, under the supervision and with the participation of our management, including our CEO and CFO, of the effectiveness of the design and operation of the disclosure controls and procedures of the Company. Based on that evaluation, our CEO and CFO concluded, as of the end of the period covered by our Form 10-K for the fiscal year ended December 31, 2021, that our disclosure controls and procedures were effective. For purposes of this statement, the term "disclosure controls and procedures" means controls and other procedures of the Company that are designed to ensure that information required to be disclosed by the Company in the reports that it files or submits under the Securities Exchange Act (15 U.S.C. 78a et seq) is recorded, processed, summarized, and reported, within the time periods specified in the Commission's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by the issuer in the reports that it files or submits under the Act is accumulated and communicated to the issuer's management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

Changes in Internal Control over Financial Reporting

There was no change during the fiscal quarter ended December 31, 2021 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Management's Annual Report on Internal Control over Financial Reporting

The Company's management, including our CEO and CFO, is responsible for establishing and maintaining adequate internal control over financial reporting (as such term is defined in Exchange Act Rule 13a-15(f) and 15d-15(f)) for the Company. The Company's internal control system was designed to provide reasonable assurance to the Company's management and Board of Directors regarding the preparation and fair presentation of published consolidated financial statements in accordance with accounting principles generally accepted in the United States of America.

Because of its inherent limitations, a system of internal control over financial reporting can provide only reasonable assurance and may not prevent or detect misstatements. Further, because of changing conditions, effectiveness of internal control over financial reporting may vary over time. The Company's processes contain self-monitoring mechanisms, and actions are taken to correct deficiencies as they are identified.

Management has assessed the effectiveness of the Company's internal control over financial reporting as of December 31, 2021, based on the criteria for effective internal control described in Internal Control — Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on its assessment, management concluded that the Company's internal control over financial reporting was effective as of December 31, 2021.

Report of Independent Registered Public Accounting Firm

Shareholders and Board of Directors
STAAR Surgical Company
Lake Forest, California

Opinion on Internal Control over Financial Reporting

We have audited STAAR Surgical Company's (the "Company's") internal control over financial reporting as of December 31, 2021, based on criteria established in Internal Control – Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (the "COSO criteria"). In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2021, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) ("PCAOB"), the consolidated balance sheets of the Company as of December 31, 2021 and January 1, 2021, the related consolidated statements of operations, comprehensive income, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2021, and the related notes and financial statement schedule and our report dated February 23, 2022 expressed an unqualified opinion thereon.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Item 9A, Management's Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit of internal control over financial reporting in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audit also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ BDO USA, LLP

Los Angeles, California

February 23, 2022

ITEM 9B. Other Information

None.

ITEM 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

None.

PART III

ITEM 10. Directors, Executive Officers and Corporate Governance

The information required by this item is incorporated herein by reference to the section entitled "*Election of Directors*" contained in the proxy statement for the 2022 annual meeting of stockholders (the "Proxy Statement") to be filed with the Securities and Exchange Commission within 120 days of the close of the fiscal year ended December 31, 2021.

ITEM 11. Executive Compensation

The information required by this item is incorporated herein by reference to the section entitled "*Executive Compensation*" contained in the Proxy Statement.

ITEM 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The information required by this item is incorporated herein by reference to the section entitled "*Security Ownership of Principal Shareholders and Management*" and "*Election of Directors*" contained in the Proxy Statement.

ITEM 13. Certain Relationships and Related Transactions, and Director Independence

The information required by this item is incorporated herein by reference to the section entitled "*Election of Directors*" contained in the Proxy Statement.

ITEM 14. Principal Accounting Fees and Services

The information required by this item is incorporated herein by reference to the section entitled "*Ratification of Independent Registered Public Accounting Firm*" contained in the Proxy Statement.

PART IV

ITEM 15. Exhibits and Financial Statement Schedules

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

		Page
(1)	**Consolidated Financial Statements**	
	Report of Independent Registered Public Accounting Firm	F-2
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(2)	**Schedules required by Regulation S-X are filed as an exhibit to this report**	
	II. Schedule II — Valuation and Qualifying Accounts and Reserves	F-40

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

(3)	**Exhibits**
3.1	Amended and Restated Certificate of Incorporation.(1)
3.2	Amended and Restated Bylaws.(2)
4.1	Form of Certificate for Common Stock, par value $0.01 per share.(3)
†4.2	Amended and Restated Omnibus Equity Incentive Plan.(4)
4.3	Description of the Registrant's Securities.(20)
10.1	Amendment No. 1 to Standard Industrial/Commercial Multi-Tenant Lease dated January 3, 2003, by and between the Company and California Rosen LLC.(5)
†10.2	Form of Indemnification Agreement between the Company and certain officers and directors.(6)
†10.3	Employment Agreement, dated December 16, 2004 by and between the Company and Hans Blickensdoerfer.(7)
10.4	Basic Agreement on Unsterilized Intraocular Lens Sales Transactions between Canon Staar Co., Inc. and Nidek Co., Ltd., dated May 23, 2005.(9)
10.5	Basic Agreement on Injector Product Sales Transactions between Canon Staar Co., Inc. and Nidek Co., Ltd., dated May 23, 2005.(9)
10.6	Memorandum of Understanding Concerning Basic Agreements for Purchase and Sale between STAAR Japan Inc. and Nidek Co., Ltd., dated December 25, 2008.(9)
10.7	Acrylic Preset Supply Warranty Agreement between STAAR Japan Inc. and Nidek Co., Ltd., dated December 25, 2008.(9)
†10.8	Form of Executive Severance Agreement.(10)
†10.9	Form of Executive Change in Control Agreement.(10)
10.10	Standard Industrial/Commercial Single – Tenant Lease – Net dated August 17, 2012, by and between the Company and Pacific Equity Partners, LLC.(11)
†10.11	Letter of the Company dated March 27, 2012 to Samuel Gesten, Vice President and General Counsel, regarding compensation.(8)
†10.12	Letter of the Company dated July 27, 2015 to Keith Holliday, Vice President of Research and Development, regarding compensation.(12)
†10.13	Employment Agreement effective March 1, 2015 by and between the Company and Caren Mason, dated March 1, 2015.(13)
10.14	Form of Option Grant and Stock Option Agreement for employees.(14)
10.15	Form of Option Grant and Stock Option Agreement for Non-Employee Directors.(14)
10.16	Form of Restricted Stock Unit Grant and Agreement.(14)
10.17	Form of Restricted Stock Award Grant and Restricted Stock Award Agreement.(14)
10.18	Lease dated August 10, 2017 by and between the Company and 2000 Gold L.P.(15)
10.19	Lease Agreement commencing May 1, 2018 between Bukewihge Properties, LLC and STAAR Surgical Company.(16)
10.20	Form of Distributorship Agreement.(6)
10.21	Lease Agreement dated January 29, 2019 between GZK Real Estate Ltd. and STAAR Surgical Ltd.(18)
10.22	Lease Agreement dated June 13, 2019 between Einfache Gesellschaft Calderari & Schwab. and STAAR Surgical AG.(19)
†10.23	Letter of the Company dated August 10, 2012 to James Francese, Vice President, Global Marketing, regarding compensation.(8)

†10.24	Employment Agreement effective October 1, 2017 by and between the Company and Scott Barnes, dated September 11 2011.(20)
†10.25	Letter of the Company dated June 30, 2020 to Patrick Williams, Chief Financial Officer, regarding compensation.(4)
10.26	Lease agreement entered into on September 14, 2020 between STAAR Surgical Company and Calderari & Schwab.(21)
10.27	First Amendment to Lease Agreement dated October 1, 2020 between STAAR Surgical Company and Pacific Equity Partners, LLC.(22)
10.28	First Amendment to Lease Agreement dated October 30, 2020 between STAAR Surgical Company and 2000 Gold L.P.(23)
14.1	Code of Business Conduct and Ethics.(17)
21.1	List of Subsidiaries.*
23.1	Consent of BDO USA, LLP.*
31.1	Certification Pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934, Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.*
31.2	Certification Pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934, Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.*
32.1	Certification Pursuant to 18 U.S.C. Section 1350, Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.**
101	The following materials from the Company's Annual Report on Form 10-K for the year ended December 31, 2021 formatted inline Extensible Business Reporting Language (iXBRL): (i) the Consolidated Balance Sheets, (ii) the Consolidated Statements of Income, (iii) the Consolidated Statements of Comprehensive Income (Loss), (iv) the Consolidated Statements of Stockholders' Equity, (v) the Consolidated Statements of Cash Flows, and (vi) related notes.
104	The cover page from the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2021, has been formatted in Inline XBRL with applicable taxonomy extension information contained in Exhibit 101.

*	Filed herewith.
**	Furnished herewith.
†	Management contract or compensatory plan.
(1)	Incorporated by reference to Appendix 2 of the Company's Proxy Statement on Form DEF 14A as filed with the Commission on April 13, 2018.
(2)	Incorporated by reference to Appendix 3 of the Company's Proxy Statement on Form DEF 14A as filed with the Commission on April 13, 2018.
(3)	Incorporated by reference to Exhibit 4.1 to Amendment No. 1 to the Company's Registration Statement on Form 8-A/A as filed with the Commission on April 18, 2003.
(4)	Incorporated by reference to the Company's Quarterly Report on Form 10-Q, for the period ended July 3, 2020, as filed with the Commission on August 5, 2020.
(5)	Incorporated by reference to the Company's Annual Report on Form 10-K, for the year ended January 2, 2004, as filed with the Commission on March 17, 2004.
(6)	Incorporated by reference from the Company's Quarterly Report on Form 10-Q, for the period ended June 29, 2018, as filed with the Commission on August 1, 2018.
(7)	Incorporated by reference to the Company's Current Report on Form 8-K as filed with the Commission on October 1, 2009.
(8)	Incorporated by reference to the Company's Annual Report on Form 10-K, for the year ended December 31, 2012, as filed with the commission on March 12, 2013.
(9)	Incorporated by reference to the Company's Annual Report on Form 10-K, for the year ended January 1, 2010 as filed with the Commission on April 1, 2010.
(10)	Incorporated by reference to the Company's Quarterly Report on Form 10-Q, for the period ended September 30, 2011, as filed with the Commission on November 2, 2011.

(11) Incorporated by reference to the Company's Current Report on Form 8-K as filed with the Commission on August 23, 2012.
(12) Incorporated by reference to the Company's Quarterly Report on Form 10-Q, for the period ended October 2, 2015, as filed with the Commission on November 4, 2015.
(13) Incorporated by reference to the Company's Current Report on Form 8-K as filed with the Commission on March 3, 2015.
(14) Incorporated by reference to the Company's Annual Report on Form 10-K, for the year ended December 30, 2016, as filed with the Commission on March 2, 2017.
(15) Incorporated by reference to the Company's Quarterly Report on Form 10-Q, for the period ended September 29, 2017, as filed with the Commission on November 8, 2017.
(16) Incorporated by reference to the Company's Quarterly Report on Form 10-Q, for the period ended March 30, 2018, as filed with the Commission on May 2, 2018.
(17) Incorporated by reference to the Company's Quarterly Report on Form 10-Q/A, for the period ended June 29, 2012, as filed with the Commission on August 8, 2012.
(18) Incorporated by reference to the Company's Quarterly Report on Form 10-Q, for the period ended March 29, 2019, as filed with the Commission on May 1, 2019.
(19) Incorporated by reference to the Company's Quarterly Report on Form 10-Q, for the period ended June 28, 2019, as filed with the Commission on July 31, 2019.
(20) Incorporated by reference to the Company's Annual Report on Form 10-K, for the year ended January 3, 2020, as filed with the Commission on February 26, 2020.
(21) Incorporated by reference to the Company's Current Report on Form 8-K as filed with the Commission on September 14, 2020.
(22) Incorporated by reference to the Company's Current Report on Form 8-K as filed with the Commission on October 8, 2020.
(23) Incorporated by reference to the Company's Quarterly Report on Form 10-Q, for the period ended October 2, 2020, as filed with the Commission on November 4, 2020.

ITEM 16. Form 10-K Summary

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

STAAR SURGICAL COMPANY

Date: February 23, 2022

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

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

Name	Title	Date
/s/ CAREN MASON Caren Mason	President, Chief Executive Officer and Director (principal executive officer)	February 23, 2022
/s/ PATRICK F. WILLIAMS Patrick F. Williams	Vice President, Chief Financial Officer (principal accounting and financial officer)	February 23, 2022
/s/ LOUIS E. SILVERMAN Louis E. Silverman	Chairman of the Board, Director	February 23, 2022
/s/ STEPHEN C. FARRELL Stephen C. Farrell	Director	February 23, 2022
/s/ THOMAS G. FRINZI Thomas G. Frinzi	Director	February 23, 2022
/s/ GILBERT H. KLIMAN Gilbert H. Kliman	Director	February 23, 2022
/s/ ELIZABETH YEU Elizabeth Yeu	Director	February 23, 2022
/s/ K. PEONY YU K. Peony Yu	Director	February 23, 2022

STAAR SURGICAL COMPANY AND SUBSIDIARIES
CONSOLIDATED FINANCIAL STATEMENTS
Years Ended December 31, 2021, January 1, 2021 and January 3, 2020

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Shareholders and Board of Directors
STAAR Surgical Company
Lake Forest, California

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of STAAR Surgical Company (the "Company") as of December 31, 2021 and January 1, 2021, the related consolidated statements of income, comprehensive income (loss), stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2021, and the related notes and financial statement schedule (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2021 and January 1, 2021, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2021, in conformity with accounting principles generally accepted in the United States of America.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) ("PCAOB"), the Company's internal control over financial reporting as of December 31, 2021, based on criteria established in Internal Control – Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO") and our report dated February 23, 2022 expressed an unqualified opinion thereon.

Change in Accounting Method Related to Leases

As discussed in Notes 1 and 9 to the consolidated financial statements, the Company has changed its method of accounting for leases during the year ended January 3, 2020 due to the adoption of the Accounting Standards Codification ("ASC") 842, "Leases."

Basis for Opinion

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

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

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

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the consolidated financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matter does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing separate opinions on the critical audit matter or on the accounts or disclosures to which it relates.

Income Tax Provision

As described in Notes 1 and 10 to the Company's consolidated financial statements, the Company operates in multiple jurisdictions through its wholly-owned subsidiaries. The Company serves international markets and is subject to income taxes in the U.S. and numerous foreign jurisdictions, which affect the Company's provision for income taxes. The tax provision is based on management's understanding of current enacted tax laws and tax rates of each tax jurisdiction and assessing the realizability of the deferred tax assets. In evaluating the Company's ability to realize the deferred tax assets management considers the positive and negative evidence, including the reversals of deferred tax assets and liabilities, projected future taxable income, tax-planning strategies, and results of recent operations.

We identified the Company's calculation of the provision for income taxes, including the judgement and estimation regarding projected taxable income as a critical audit matter. Management is required to apply significant judgments in calculating the provision for income taxes related to the evaluation of tax laws, including the methods used to allocate taxable income to various jurisdictions and the development of forecasts and assumptions related to the projected sales growth, margins, costs and income that are used to assess the realizability of deferred tax assets. These forecasts include various assumptions including the likelihood of continued growth in certain key markets, projected industry-wide performance, macro-economic factors and the development and approval of new products. Auditing these elements involved especially complex auditor judgment due to the nature of audit evidence and extent of audit effort required to address these matters, including the need to involve personnel with specialized knowledge and skills.

The primary procedures we performed to address this critical audit matter included:

- Testing the design and operating effectiveness of controls over management's calculation of its provision for income taxes, including controls over: (i) reviewing the assumptions and data utilized in determining the allocation of income to applicable tax jurisdictions, (ii) the development of the projected forecasts, and (iii) projected reversals of deferred tax assets and liabilities in the valuation allowance assessment.
- Assessing the reasonableness of the Company's projected forecasts and related assumptions against the Company's historical performance, industry-wide performance, macro-economic factors, and evidence obtained in other areas of the audit.
- Recalculating income tax expense and agreeing the data used in the calculations to the Company's underlying books and records.
- Utilizing personnel with specialized knowledge and skills in domestic and international tax law to assist in: (i) evaluating the application of tax laws used in management's allocation methodologies based on the Company's structure and operations, (ii) evaluating transfer pricing regulations to assist in assessing the appropriateness of intercompany transactions and the rates used to cross charge and allocate costs based on transfer pricing agreements, (iii) recalculating the income tax expense utilizing enacted tax rates, and (iv) evaluating both positive and negative evidence and assessing the reasonableness of assumptions used in the Company's valuation allowance assessment.

/s/ BDO USA, LLP

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

Los Angeles, California
February 23, 2022

STAAR SURGICAL COMPANY AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS
December 31, 2021 and January 1, 2021

(In thousands, except par value amounts)

	2021	2020
ASSETS		
Current assets:		
Cash and cash equivalents	$ 199,706	$ 152,453
Accounts receivable trade, net	43,531	35,229
Inventories, net	17,274	18,111
Prepayments, deposits and other current assets	10,900	10,625
Total current assets	271,411	216,418
Property, plant and equipment, net	35,912	24,030
Finance lease right-of-use assets, net	506	596
Operating lease right-of-use assets, net	31,310	8,764
Intangible assets, net	218	270
Goodwill	1,786	1,786
Deferred income taxes	3,813	4,944
Other assets	822	608
Total assets	$ 345,778	$ 257,416
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Line of credit	$ —	$ 1,379
Accounts payable	8,699	7,474
Obligations under finance leases	127	360
Obligations under operating leases	3,283	2,485
Allowance for sales returns	4,816	4,532
Other current liabilities	31,877	25,006
Total current liabilities	48,802	41,236
Obligations under finance leases	382	38
Obligations under operating leases	28,269	6,537
Deferred income taxes	811	222
Asset retirement obligations	198	221
Pension liability	8,758	11,940
Total liabilities	87,220	60,194
Commitments and contingencies (Note 13)		
Stockholders' equity:		
Common stock, $0.01 par value; 60,000 shares authorized: 47,716 and 46,488 shares issued and outstanding at December 31, 2021 and January 1, 2021, respectively	477	464
Additional paid-in capital	373,519	338,194
Accumulated other comprehensive loss	(4,048)	(5,545)
Accumulated deficit	(111,390)	(135,891)
Total stockholders' equity	258,558	197,222
Total liabilities and stockholders' equity	$ 345,778	$ 257,416

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

STAAR SURGICAL COMPANY AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF INCOME
Years Ended December 31, 2021, January 1, 2021 and January 3, 2020

(In thousands, except per share amounts)

	2021	2020	2019
Net sales	$ 230,472	$ 163,460	$ 150,185
Cost of sales	51,835	45,098	38,231
Gross profit	178,637	118,362	111,954
Selling, general and administrative expenses:			
General and administrative	44,142	33,911	29,313
Selling and marketing	67,294	45,764	45,491
Research and development	33,862	31,918	25,298
Total selling, general and administrative expenses	145,298	111,593	100,102
Operating income	33,339	6,769	11,852
Other income (expense), net:			
Interest income (expense), net	(38)	238	988
Gain (loss) on foreign currency transactions	(2,964)	864	(517)
Royalty income	1,015	440	551
Other income (loss), net	(48)	(44)	152
Total other income (expenses), net	(2,035)	1,498	1,174
Income before income taxes	31,304	8,267	13,026
Provision (benefit) for income taxes	6,803	2,354	(1,022)
Net income	$ 24,501	$ 5,913	$ 14,048
Net income per share:			
Basic	$ 0.52	$ 0.13	$ 0.32
Diluted	$ 0.50	$ 0.12	$ 0.30
Weighted average shares outstanding:			
Basic	47,210	45,605	44,493
Diluted	49,456	47,953	46,895

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

STAAR SURGICAL COMPANY AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)
Years Ended December 31, 2021, January 1, 2021 and January 3, 2020

(In thousands)

	2021	2020	2019
Net income	$ 24,501	$ 5,913	$ 14,048
Other comprehensive income (loss):			
Defined benefit plans:			
Net change in plan assets	2,632	(3,639)	(2,265)
Reclassification into other income (expense), net	487	283	107
Foreign currency translation gain (loss)	(1,776)	717	291
Tax effect	154	142	139
Other comprehensive income (loss), net of tax	1,497	(2,497)	(1,728)
Comprehensive income	$ 25,998	$ 3,416	$ 12,320

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

STAAR SURGICAL COMPANY AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
Years Ended December 31, 2021, January 1, 2021 and January 3, 2020

(In thousands)

	Common Stock Shares	Common Stock Par Value	Additional Paid-In Capital	Accumulated Other Compre-hensive Income (Loss)	Accumulated Deficit	Total
Balance, at December 28, 2018	44,195	$ 442	$ 289,584	$ (1,320)	$ (156,280)	$ 132,426
Net income	—	—	—	—	14,048	14,048
Impact of the adoption of lease accounting standard	—	—	—	—	113	113
Impact of adoption of nonemployee share-based payment standard	—	—	(315)	—	315	—
Other comprehensive loss	—	—	—	(1,728)	—	(1,728)
Common stock issued upon exercise of options	387	4	3,455	—	—	3,459
Stock-based compensation	—	—	11,564	—	—	11,564
Unvested restricted stock	11	—	—	—	—	—
Vested restricted stock	229	2	—	—	—	2
Balance, at January 3, 2020	44,822	448	304,288	(3,048)	(141,804)	159,884
Net income	—	—	—	—	5,913	5,913
Other comprehensive loss	—	—	—	(2,497)	—	(2,497)
Common stock issued upon exercise of options	1,507	15	20,631	—	—	20,646
Stock-based compensation	—	—	13,275	—	—	13,275
Unvested restricted stock	11	—	—	—	—	—
Vested restricted stock	108	1	—	—	—	1
Balance, at January 1, 2021	46,448	464	338,194	(5,545)	(135,891)	197,222
Net income	—	—	—	—	24,501	24,501
Other comprehensive income	—	—	—	1,497	—	1,497
Common stock issued upon exercise of options	1,206	12	19,425	—	—	19,437
Stock-based compensation	—	—	15,900	—	—	15,900
Unvested restricted stock	3	—	—	—	—	—
Vested restricted stock	59	1	—	—	—	1
Balance, at December 31, 2021	47,716	$ 477	$ 373,519	$ (4,048)	$ (111,390)	$ 258,558

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

STAAR SURGICAL COMPANY AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS
Years Ended December 31, 2021, January 1, 2021 and January 3, 2020

(In thousands)

	2021	2020	2019
Cash flows from operating activities:			
Net income	$ 24,501	$ 5,913	$ 14,048
Adjustments to reconcile net income to net cash provided by operating activities:			
Depreciation of property, plant, and equipment	3,608	3,060	3,665
Amortization of intangibles	34	35	34
Deferred income taxes	1,495	(849)	(3,481)
Change in net pension liability	137	656	359
Loss on disposal of property and equipment	2	213	14
Stock-based compensation expense	14,605	12,146	10,547
Provision for sales returns and bad debts	318	835	275
Inventory provision	1,654	1,706	1,580
Changes in working capital:			
Accounts receivable	(8,868)	(3,974)	(4,502)
Inventories	66	(1,390)	(950)
Prepayments, deposits, and other current assets	(711)	(3,753)	(1,313)
Accounts payable	108	(1,199)	1,084
Other current liabilities	7,013	7,552	4,435
Net cash provided by operating activities	43,962	20,951	25,795
Cash flows from investing activities:			
Acquisition of property and equipment	(13,645)	(8,404)	(10,095)
Acquisition of patents and licenses	—	—	(83)
Net cash used in investing activities	(13,645)	(8,404)	(10,178)
Cash flows from financing activities:			
Repayment of finance lease obligations	(348)	(561)	(1,294)
Repayment of line of credit	(1,297)	(515)	(2,018)
Proceeds from the exercise of stock options	19,437	20,646	3,459
Proceeds from vested restricted stock	1	1	2
Net cash provided by financing activities	17,793	19,571	149
Effect of exchange rate changes on cash and cash equivalents	(857)	367	203
Increase in cash and cash equivalents	47,253	32,485	15,969
Cash and cash equivalents, at beginning of year	152,453	119,968	103,999
Cash and cash equivalents, at end of year	$ 199,706	$ 152,453	$ 119,968

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

Note 1 — Organization and Description of Business and Accounting Policies

Organization and Description of Business

STAAR Surgical Company and subsidiaries (the "Company"), a Delaware corporation, was first incorporated in 1982 for the purpose of developing, producing, and marketing implantable lenses for the eye and delivery systems used to deliver the lenses into the eye. Principal products are implantable Collamer lenses ("ICLs") and intraocular lenses ("IOLs"). ICLs, consisting of the Company's ICL family of products, including the Toric implantable Collamer lenses ("TICL") and EVO+ Visian ICL, are intraocular lenses used to correct refractive conditions such as myopia (near-sightedness), hyperopia (far-sightedness), astigmatism, and presbyopia. IOLs are prosthetic intraocular lenses used to restore vision that has been adversely affected by cataracts, and include the Company's lines of silicone IOLs and the Preloaded Injector (a silicone or acrylic IOL preloaded into a single-use disposable injector).

As of December 31, 2021, the Company's significant subsidiaries consisted of:

- STAAR Surgical AG, a wholly owned subsidiary formed in Switzerland that markets and distributes ICLs and Preloaded IOLs.
- STAAR Japan, a wholly owned subsidiary that markets and distributes Preloaded IOLs and ICLs.

The Company operates as one operating segment, the ophthalmic surgical market, for financial reporting purposes (see Note 17).

Principles of Consolidation

The accompanying consolidated financial statements include the accounts of STAAR Surgical Company and its wholly-owned subsidiaries and have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP"). All significant intercompany balances and transactions have been eliminated. Certain reclassifications have been made to financial statements of prior years to conform to the current year presentation (see Note 20).

Fiscal Year and Interim Reporting Periods

The Company's fiscal year ends on the Friday nearest December 31 and each of the Company's quarterly reporting periods generally consists of 13 weeks. Fiscal years 2021 and 2020 are based on a 52-week period and fiscal year 2019 is based on a 53-week period.

Foreign Currency

The functional currency of STAAR Japan is the Japanese yen. The functional currency of STAAR Surgical AG is the U.S. dollar.

Assets and liabilities of STAAR Japan are translated at rates of exchange in effect at the close of the period. Sales and expenses are translated at the weighted average of exchange rates in effect during the period. Net foreign translation gain (loss) was as follows (in thousands):

	Years Ended		
	2021	2020	2019
Foreign currency translation gain (loss)(1)	$ (1,776)	$ 717	$ 291
Gain (loss) on foreign currency transactions(2)	(2,964)	864	(517)

(1) Shown as a separate line item on the Consolidated Statements of Comprehensive Income (Loss).
(2) Shown as a separate line item on the Consolidated Statements of Income.

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

Use of Estimates

The consolidated financial statements have been prepared in conformity with GAAP and, as such, include amounts based on significant estimates and judgments of management with consideration given to materiality. Significant estimates used include determining valuation allowances for uncollectible trade receivables, sales returns reserves, obsolete and excess inventory reserves, deferred income taxes, and tax reserves, including valuation allowances for deferred tax assets, pension liabilities, evaluation of asset impairment, in determining the useful life of depreciable and definite-lived intangible assets, and in the variables and assumptions used to calculate and record stock-based compensation. Actual results could differ materially from those estimates.

Cash and Cash Equivalents

Cash and cash equivalents include cash and balances on deposit in banks and financial institutions. The Company considers all highly liquid investments purchased with a maturity of three months or less to be cash equivalents. Such balances generally exceed the federal insurance limits; however, the Company periodically assesses the financial condition of the institutions and believes that the risk of any loss is minimal.

Revenue Recognition

The Company recognizes revenue when its contractual performance obligations with customers are satisfied. The Company's performance obligations are generally limited to single sales orders with product shipping to the customer within a month of receipt of the sales order. Substantially all of the Company's revenues are recognized at a point-in-time when control of its products transfers to the customer, which is typically upon shipment (as discussed below). The Company presents sales tax and similar taxes it collects from its customers on a net basis (excluded from revenues).

The Company sells certain injector parts to an unrelated customer and supplier (collectively referred to as "supplier") whereby these injector part sales are either made as a final sale to the supplier or, are sold to be combined with an acrylic cataract IOL by the supplier into finished goods inventory (a preloaded acrylic cataract IOL). These finished goods are then sold back to the Company at an agreed upon, contractual price. The Company makes a profit margin on either type of sale with the supplier and each type of sale is made under separate purchase and sales orders between the two parties resulting in cash settlement for the orders sold or repurchased. For parts that are sold as a final sale, the Company recognizes a sale and those sales are classified as other product sales in total net sales. For the injector parts that are sold to be combined with an acrylic cataract IOL into finished goods, the Company records the transaction at its carrying value deferring any profit margin as contra-inventory, until the finished goods inventory is sold to an end-customer (not the supplier) at which point the Company recognizes revenues.

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

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

Revenue Recognition (Continued)

The Company also enters into certain strategic cooperation agreements with customers in which, as consideration for certain commitments made by the customer, including minimum purchase commitments, the Company agrees, among other things, to pay for marketing, educational training and general support of the Company's products. The provisions in these arrangements allow for these payments to be made directly to the customer or payments can be made directly to a third party for distinct marketing, educational training and general support services provided to or on behalf of the customer by the third party. For payments the Company makes to another party, or reimburses the customer for distinct marketing and support services, the Company recognizes these payments as sales and marketing expense as incurred in accordance with ASC 606-10-32-25. These strategic cooperation agreements are generally for periods of 12 months or more with quarterly minimum purchase commitments. The Company recognizes sales and marketing expenses in the period in which it expects the customer will achieve its minimum purchase commitment, generally quarterly, and any unpaid amounts are recorded in Other Current Liabilities on the Consolidated Balance Sheets, see Note 7. Reimbursements made directly to the customer for general marketing incentives are treated as a reduction in revenues. The Company's performance obligations generally occur in the same quarter as the shipment of product. Sales and marketing expenses for distinct services were as follows (in thousands):

	Years Ended		
	2021	2020	2019
Marketing and support services related to strategic cooperation agreements	$ 714	$ 655	$ 485

Since the payments for distinct or non-distinct services occur within the quarter corresponding with the purchases made by the customer and the shipments made by the Company to that customer, there is no remaining performance obligation by the Company to the customer. Accordingly, there are no deferred revenues associated with these types of arrangements as of December 31, 2021, January 1, 2021 and January 3, 2020.

The Company disaggregates its revenue into the following categories: non-consignment sales and consignment sales.

- Non-consignment Sales – The Company recognizes revenue from non-consignment product sales at a point-in-time when control has been transferred, which is typically at shipping point, except for certain customers and for STAAR Japan, which is typically recognized when the customer receives the product. The Company does not have significant deferred revenues as of December 31, 2021, January 1, 2021 and January 3, 2020, as delivery to the customer is generally made within the same or the next day of shipment.
- Consignment Sales – The Company's products are marketed to ophthalmic surgeons, hospitals, ambulatory surgery centers or vision centers, and distributors. Cataract IOLs and ICLs may be offered to surgeons and hospitals on a consignment basis. The Company maintains title and risk of loss on consigned inventory and recognizes revenue for consignment inventory at a point-in-time when the Company is notified that the lenses have been implanted, thus completing the performance obligation.

See Note 17 for additional information on disaggregation of revenues, geographic sales information and product sales.

Allowance for Doubtful Accounts

The Company performs ongoing credit evaluations of its customers and adjusts credit limits based on customer payment history and credit worthiness, as determined by the Company's review of its customers' current credit information. The Company continuously monitors collections and payments from customers and maintains a provision for estimated credit losses and uncollectible accounts based upon an expected loss model which considers its historical experience, any specific customer collection issues that have been identified and other relevant observable data, including current economic conditions. Amounts determined to be uncollectible are written off against the allowance for doubtful accounts.

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

Concentration of Credit Risk and Revenues

Financial instruments that potentially subject the Company to credit risk principally consist of trade receivables. This risk is limited due to the large number of customers comprising the Company's customer base, and their geographic dispersion. As of December 31, 2021 and January 1, 2021, there was one customer who accounted for 47% and 46% of the Company's consolidated trade receivables, respectively. Ongoing credit evaluations of customers' financial condition are performed and, generally, no collateral is required. The Company maintains reserves for potential credit losses and such losses, taken together, have not exceeded management's expectations.

There was one customer who accounted for 47%, 44% and 43% of the Company's consolidated net sales for the years ended 2021, 2020 and 2019, respectively.

Sales Return Reserve

The Company generally may permit returns of product if the product, upon issuance of a Return Goods Authorization, is returned within the time allowed by its return policies and records an allowance for estimated returns at the time revenue is recognized. The Company's allowance for estimated returns is based on an expected loss model which considers historical and current/anticipated trends and experience, the impact of new product launches, the entry of a competitor, availability of timely and pertinent information and the various terms and arrangements offered, including sales with extended credit terms. For estimated returns, sales are reported net of estimated returns and cost of sales are reported net of estimated returns that can be resold. On the Consolidated Balance Sheets, the balances associated for estimated sales returns were as follows (in thousands):

	2021	2020
Estimated returns - inventory[1]	$ 814	$ 1,041
Allowance for sales returns	4,816	4,532

(1) Recognized in inventories, net on the Consolidated Balance Sheets

Fair Value of Financial Instruments

Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. To increase the comparability of fair value measures, the following hierarchy prioritizes the inputs to valuation methodologies used to measure fair value (ASC 820-10-50):

- Level 1 – Inputs to the valuation methodology are quoted prices (unadjusted) for identical assets or liabilities in active markets.
- Level 2 – Inputs to the valuation methodology include quoted prices for similar assets or liabilities in active markets, and inputs that are observable for the assets or liability, either directly or indirectly, for substantially the full term of the financial instruments.
- Level 3 – Inputs to the valuation methodology are unobservable; that reflect management's own assumptions about the assumptions market participants would make and significant to the fair value.

The carrying values reflected on the Consolidated Balance Sheets for cash and cash equivalents, trade accounts receivable, net, prepayments, deposits and other current assets, accounts payable, other current liabilities and line of credit approximate their fair values because of the short maturity of these instruments.

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

Inventories, Net

Inventories, net are valued at the lower of cost, determined on a first-in, first-out basis, or net realizable value. Inventories include the costs of raw material, labor, and manufacturing overhead, work in process and finished goods. Inventories also include as a contra item, deferred margins for certain injector parts described under the revenue recognition policy. The Company provides estimated inventory allowances for excess, expiring, slow moving and obsolete inventory as well as inventory whose carrying value is in excess of net realizable value to properly reflect inventory at the lower of cost or market.

Property, Plant, and Equipment

Property, plant, and equipment are recorded at cost. Depreciation on property, plant, and equipment is computed using the straight-line method over the estimated useful lives of the assets as noted below. Leasehold improvements are amortized over the lesser of the estimated useful lives of the assets or the related expected lease term. Major improvements are capitalized and minor replacements, maintenance and repairs are charged to expense as incurred.

Also included in property, plant and equipment is construction in process. Construction in process includes the cost of design plans and build out of facilities and the cost of equipment, as well as the direct costs incurred in the testing and validation of machinery and equipment and facilities before they are ready for productive use. Upon placement in service, costs are reclassified into the appropriate asset category and depreciation commences.

The estimated useful lives of assets are as follows:

Machinery and equipment	5-10 years
Computer equipment and software	2-5 years
Furniture and equipment	3-7 years
Leasehold improvements	The shorter of the useful life of the asset or the expected term of the associated lease

Goodwill

Goodwill, which has an indefinite life, is not amortized but instead is tested for impairment on an annual basis or between annual tests if an event occurs or circumstances change that would indicate the carrying amount may be impaired. Impairment testing for goodwill is done at the reporting unit level. Reporting units can be one level below the operating segment level, and can be combined when reporting units within the same operating segment have similar economic characteristics. The Company has determined that its reporting units have similar economic characteristics, and therefore, can be combined into one reporting unit for the purposes of goodwill impairment testing. The Company performed its annual impairment test and determined that its goodwill was not impaired. As of December 31, 2021 and January 1, 2021, the carrying value of goodwill was $1,786,000.

Long-Lived Assets

The Company reviews property, plant, and equipment and intangible assets, excluding goodwill, for impairment whenever events or changes in circumstances indicate the carrying amount of an asset may not be recoverable. The Company measures recoverability of these assets by comparing the carrying value of such assets to the estimated undiscounted future cash flows the assets are expected to generate. When the estimated undiscounted future cash flows are less than their carrying amount, an impairment loss is recognized equal to the difference between the assets' fair value and their carrying value. A review of long-lived assets was conducted as of December 31, 2021 and January 1, 2021 and no impairment was identified.

Amortization is computed on the straight-line basis, which is the Company's best estimate of the economic benefits realized over the estimated useful lives of the assets which range from 3 to 20 years for patents, certain acquired rights and licenses, 10 years for customer relationships, and 3 to 10 years for developed technology.

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

Lease Accounting

On December 29, 2018 (beginning of fiscal year 2019), the Company adopted FASB Accounting Standards Update ("ASU") 2016-02, "Leases (Topic 842)" and its subsequent amendments affecting the Company: (i) ASU 2018-10, "Codification Improvements to Topic 842, Leases," and (ii) ASU 2018-11, "Leases (Topic 842): Targeted improvements," using the modified retrospective method. Upon adoption of Topic 842, the Company recognized a cumulative adjustment of $113,000 which decreased the accumulated deficit and recognized right-of-use ("ROU") assets and lease liabilities for operating leases, whereby the Company's accounting finance leases remained substantially unchanged.

The Company recognizes ROU assets and lease liabilities for leases with terms greater than twelve months on the Consolidated Balance Sheets. Leases are classified as either finance or operating, with classification affecting the pattern of expense recognition in the Consolidated Statements of Income.

A contract contains a lease if the contract conveys the right to control an identified asset for a period of time in exchange for consideration. An asset is either explicitly identified or implicitly identified and must be physically distinct. In addition, the Company must have both the right to obtain substantially all of the economic benefits from use of the identified asset and has the right to direct the use of the identified asset.

Certain leases may have non-lease components such as common area maintenance expense for building leases and maintenance expenses for automobile leases. In general, the Company separates common area maintenance expense component from the value of the ROU asset and lease liability when evaluating rental properties under Topic 842, whereas, the Company includes the maintenance and service components in the value of the ROU asset and lease liability while evaluating automobile leases under Topic 842.

When determining whether a lease is a finance lease or an operating lease, Topic 842 does not specifically define criteria to determine "major part of remaining economic life of the underlying asset" and "substantially all of the fair value of the underlying asset." For lease classification determination, the Company continues to use (i) greater than or equal to 75% to determine whether the lease term is a major part of the remaining economic life of the underlying asset and (ii) greater than or equal to 90% to determine whether the present value of the sum of lease payments is substantially all of the fair value of the underlying asset.

The Company uses either the rate implicit in the lease or its incremental borrowing rate as the discount rate in lease accounting.

When adopting Topic 842, the Company did not reassess any expired or existing contracts, reassess the lease classification for any expired or existing leases and reassess initial direct costs for exiting leases. The Company also elected not to capitalize leases that have terms of twelve months or less.

The Company reviews ROU assets, for impairment whenever events or changes in circumstances indicate the carrying amount of an asset may not be recoverable. The Company measures recoverability of these assets by comparing the carrying value of such assets to the estimated undiscounted future cash flows the assets are expected to generate. When the estimated undiscounted future cash flows are less than their carrying amount, an impairment loss is recognized equal to the difference between the assets' fair value and their carrying value.

Vendor Concentration

As of December 31, 2021 there were no vendors who accounted for over 10% of the Company's consolidated accounts payable. As of January 1, 2021 there was one vendor who accounted for 10% of the Company's consolidated accounts payable. There were no vendors who accounted for over 10% of the Company's consolidated purchases for the years ended 2021 and 2020 and 2019, respectively.

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

Research and Development Costs

Expenditures for research activities relating to product development and improvement are charged to expense as incurred.

Advertising Costs

Advertising costs, which are included in marketing and selling expenses, are expensed as incurred, and were as follows (in thousands):

	Years Ended		
	2021	2020	2019
Advertising costs	$ 21,989	$ 11,081	$ 11,875

Income Taxes

The 2017 Tax Act subjects a U.S. shareholder to tax on Global Intangible Low Tax Income ("GILTI") earned by certain foreign subsidiaries. In January 2018, the FASB released guidance (Staff Q&A Topic 740, No. 5) on the accounting for tax on the GILTI provisions of the 2017 Tax Act. In general, GILTI is the excess of a U.S. shareholder's total net foreign income over a deemed return on tangible assets. The provision further allows a deduction of 50 percent of GILTI, however this deduction is limited by the Company's net operating loss carryforwards. In addition, Staff Q&A Topic 740, No. 5 states that an entity can make an accounting policy election to either recognize deferred taxes for temporary basis differences expected to reverse as GILTI in future years or to provide for the tax expense related to GILTI in the year the tax is incurred as a period expense only. The Company has elected to account for GILTI as a current period expense when incurred.

The Company recognizes the income tax benefit from an uncertain tax position when it is more likely than not that, based on technical merits, the position will be sustained upon examination, including resolutions of any related appeals or litigation processes. The amount of tax benefit recorded, if any, is limited to the extent it is not greater than 50 percent likely to be realized upon settlement with the taxing authority (that has full knowledge of all relevant information). Accrued interest, if any, related to uncertain tax positions is included as a component of income tax expense, and penalties, if incurred, are recognized as a component of operating income or loss. The Company does not have any uncertain tax positions as of any of the periods presented.

The Company did not incur significant interest and penalties for any period presented.

The Company recognizes deferred tax assets and liabilities for temporary differences between the financial reporting basis and the tax basis of the Company's assets and liabilities, net operating loss and credit carryforwards, and uncertainty in income taxes, on a jurisdiction-by-jurisdiction basis. In evaluating the Company's ability to recover the deferred tax assets within a jurisdiction from which they arise, management considers all available positive and negative evidence, including scheduled reversals of deferred tax liabilities, projected future taxable income, tax-planning strategies, and results of recent operations. In projecting future taxable income, the Company begins with historical results and incorporates assumptions including overall current and projected business and industry conditions, the amount of future federal, state, and foreign pretax operating income, the reversal of temporary differences and the successful implementation of feasible and prudent tax-planning strategies. These assumptions require significant judgment about the forecasts of future taxable income and are consistent with the plans and estimates the Company uses to manage the underlying businesses. In evaluating the objective evidence that historical results provide, the Company also considers three years of cumulative operating results. Valuation allowances, or reductions to deferred tax assets, are recognized if, based on the weight of all the available evidence, it is more likely than not that some portion or all the deferred tax asset may not be realized. The impact on deferred taxes of changes in tax rates and laws, if any, are applied to the years during which temporary differences are expected to be settled and reflected in the financial statements in the period of enactment.

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

Income Taxes (Continued)

The Company has made a policy election to apply the incremental cash tax savings approach when analyzing the impact GILTI could have on its U.S. valuation allowance. As a result of future expected GILTI inclusions, and because of the 2017 Tax Act's ordering rules, U.S. companies may now expect to utilize tax attribute carryforwards (e.g., net operating losses and deferred tax assets) for which a valuation allowance has historically been recorded (this is referred to as the "tax law ordering approach"). However, due to the mechanics of the GILTI rules, companies that have a GILTI inclusion may realize a reduced (or no) cash tax savings from utilizing such tax attribute carryforwards (this view is referred to as the "incremental cash tax savings approach").

On July 23, 2020, the U.S. Treasury issued final regulations for addressing the treatment of foreign income that is subject to a high rate of foreign tax (the GILTI high-tax exclusion). The final regulations allow companies to exclude certain high-taxed income from their GILTI calculation. The GILTI high-tax exclusion applies if the effective foreign tax rate is 90% or more of the rate that would apply if the income were subject to the maximum US rate of tax specified in section 11 (currently 18.9%, based on a maximum rate of 21%). The final regulations also provide that the GILTI high-tax exclusion is an annual election made each year and is retroactive to years beginning after December 31, 2017. The Company has made the election to exclude certain high-taxed income from its GILTI calculation for fiscal years 2021, 2020 and 2019. The Company will continue to make the election each year to the extent it results in a tax benefit.

On March 27, 2020, the Coronavirus Aid, Relief and Economic Security ("CARES") Act was enacted and signed into law. The Company reviewed the provisions of the CARES Act. The Company did not apply for or require financing available under the CARES Act. The Company does not expect it to have a material impact to its tax provision.

On December 27, 2020 the Consolidated Appropriations Act ("CAA") was enacted and signed into law. The Company reviewed the provisions of the CAA. The Company does not expect it to have a material impact to its tax provision.

On January 2, 2021 (beginning of fiscal year 2021), the Company adopted ASU 2019-12, "Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes," which removes the following exceptions: exception to the incremental approach for intraperiod tax allocation; exception to accounting for basis differences when there are ownership changes in foreign investments; and exception to interim period tax accounting for year-to-date losses that exceed anticipated losses. ASU 2019-12 also improves financial reporting for franchise taxes that are partially based on income; transactions with a government that result in a step up in the tax basis of goodwill; separate financial statements of legal entities that are not subject to tax; and enacted changes in tax laws in interim periods. The Company's adoption of ASU 2019-12 did not have material impact on Consolidated Financial Statements.

Basic and Diluted Net Income Per Share

The Company has only one class of common stock and no participating securities which would require the two-class method of calculating basic earnings per share. Basic per share information is calculated by dividing net income by the weighted average number of shares outstanding, net of unvested restricted stock, unvested restricted stock units ("RSUs") and unvested performance stock units ("PSUs"), during the period. Diluted per share information is calculated by dividing net income by the weighted average number of shares outstanding, adjusted for the effects of potentially dilutive common stock, which are comprised of outstanding warrants, stock options, unvested restricted stock, RSUs and PSUs, during the period, using the treasury-stock method (See Note 16).

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

Employee Defined Benefit Plans

The Company maintains a passive pension plan (the "Swiss Plan") covering employees of STAAR Surgical AG. The Swiss Plan conforms to the features of a defined benefit plan.

The Company also maintains a noncontributory defined benefit pension plan which covers substantially all the employees of STAAR Japan.

The Company recognizes the funded status, or difference between the fair value of plan assets and the projected benefit obligations of the pension plan on the Consolidated Balance Sheets, with a corresponding adjustment to accumulated other comprehensive income (loss). If the projected benefit obligation exceeds the fair value of plan assets, then that difference or unfunded status represents the pension liability. The Company records a net periodic pension cost in the Consolidated Statements of Income. The liabilities and annual income or expense of both plans are determined using methodologies that involve several actuarial assumptions, the most significant of which are the discount rate and the expected long-term rate of asset return (asset returns and fair-value of plan assets are applicable for the Swiss Plan only). The fair values of plan assets are determined based on prevailing market prices (see Note 11).

Stock-Based Compensation

Stock-based compensation expense for all stock-based compensation awards granted is based on the grant-date fair value. The Company recognizes these compensation costs on a straight-line basis over the requisite service period of the award, which is generally the option vesting term of three to four years for executive officers and employees, and one year for members of its Board of Directors (the "Board") (see Note 12).

The Company also, at times, issues restricted stock to its executive officers, employees and the Board, which are restricted and unvested common shares issued at fair market value on the date of grant. For the restricted shares issued to the Board, the restricted stock vests over a one-year service period, for executive officers and employees, it is typically a three-year service period, and are subject to forfeiture (or acceleration, depending upon the circumstances) until vested or the service period is completed. Restricted stock compensation expense is recognized on a straight-line basis over the requisite service period of one to three years, based on the grant-date fair value of the stock. Restricted stock is considered legally issued and outstanding on the grant date (see Notes 12 and 16).

The Company issues RSUs and PSUs (see Note 12), which can have only a service condition or a performance contingent restricted stock award based upon the Company meeting certain internally established performance conditions that vest only if those conditions are met or exceeded and the grantee is still employed with the Company. RSU and PSU compensation expense is recognized on a straight-line basis over the requisite service period. The Company recognizes compensation cost for the performance condition RSUs and PSUs when the Company concludes that it is probable that the performance condition will be achieved, net of an estimate of pre-vesting forfeitures, over the requisite service period based on the grant-date fair value of the stock. The Company reassesses the probability of vesting at each reporting period and adjusts compensation cost based on its probability assessment.

Once the RSUs and PSUs are vested, equivalent common shares will be issued or issuable to the grantee and therefore the RSUs and PSUs are not included in total common shares issued and outstanding until vested (see Notes 12 and 16).

On December 29, 2018 (beginning of fiscal year 2019), the Company adopted ASU 2018-07, "Compensation-Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting," aligns the accounting for share-based payments to nonemployees similar to employees. Upon the adoption of ASU 2018-07, the Company recognized a cumulative adjustment of $315,000 which decreased the accumulated deficit.

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

Comprehensive Income (Loss)

The Company presents comprehensive income (loss) on the Consolidated Balance Sheets and the Consolidated Statements of Comprehensive Income (Loss). Total comprehensive income (loss) includes, in addition to the net income, changes in equity that are excluded from the Consolidated Statements of Income and are recorded directly into a separate section of stockholders' equity on the Consolidated Balance Sheets. The following table summarizes the changes in the accumulated balances for each component of accumulated other comprehensive income (loss) attributable to the Company for the years ended December 31, 2021, January 1, 2021 and January 3, 2020 (in thousands):

	Foreign Currency Translation	Defined Benefit Pension Plan – Japan	Defined Benefit Pension Plan – Switzerland	Accumulated Other Comprehensive Income (Loss)
Balance, at December 28, 2018	$ 446	$ 10	$ (1,776)	$ (1,320)
Other comprehensive income (loss)	291	34	(2,192)	(1,867)
Tax effect	(86)	(6)	231	139
Balance, at January 3, 2020	651	38	(3,737)	(3,048)
Other comprehensive income (loss)	717	(33)	(3,323)	(2,639)
Tax effect	(217)	10	349	142
Balance, at January 1, 2021	1,151	15	(6,711)	(5,545)
Other comprehensive income (loss)	(1,776)	254	2,865	1,343
Tax effect	537	(77)	(306)	154
Balance, at December 31, 2021	$ (88)	$ 192	$ (4,152)	$ (4,048)

Note 2 — Accounts Receivable Trade, Net

Accounts receivable trade, net consisted of the following (in thousands):

	2021	2020
Domestic	$ 1,210	$ 828
Foreign	42,364	34,460
Total accounts receivable trade, gross	43,574	35,288
Less allowance for doubtful accounts	(43)	(59)
Total accounts receivable trade, net	$ 43,531	$ 35,229

Note 3 — Inventories, Net

Inventories, net consisted of the following (in thousands):

	2021	2020
Raw materials and purchased parts	$ 3,971	$ 3,679
Work in process	4,031	2,174
Finished goods	10,429	13,717
Total inventories, gross	18,431	19,570
Less inventory reserves	(1,157)	(1,459)
Total inventories, net	$ 17,274	$ 18,111

Note 4 — Prepayments, Deposits and Other Current Assets

Prepayments, deposits and other current assets consisted of the following (in thousands):

	2021	2020
Prepayments and deposits	$ 4,047	$ 3,423
Prepaid insurance	2,647	2,677
Consumption tax receivable	830	1,409
Value added tax (VAT) receivable	2,197	2,056
Other[1]	1,179	1,060
Total prepayments, deposits and other current assets	$ 10,900	$ 10,625

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

Note 5 — Property, Plant and Equipment, Net

Property, plant and equipment, net consisted of the following (in thousands):

	2021	2020
Machinery and equipment	$ 24,127	$ 21,209
Computer equipment and software	8,807	7,423
Furniture and fixtures	3,658	4,676
Leasehold improvements	11,821	11,388
Construction in process	21,827	11,120
Total property, plant and equipment, gross	70,240	55,816
Less accumulated depreciation	(34,328)	(31,786)
Total property, plant and equipment, net	$ 35,912	$ 24,030

Depreciation expense and loss on disposal of property, plant and equipment were as follows (in thousands):

	Years Ended		
	2021	2020	2019
Depreciation expense	$ 3,525	$ 2,801	$ 3,081
Loss on disposal of property, plant and equipment	2	213	14

The loss recognized for the year ended January 1, 2021 consisted primarily of an asset, with a net book value of $208,000, that was no longer in use.

Note 6 — Intangible Assets, Net

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

	2021			2020		
Long-lived amortized intangible assets	**Gross Carrying Amount**	**Accumulated Amortization**	**Net**	**Gross Carrying Amount**	**Accumulated Amortization**	**Net**
Patents and licenses	$ 9,315	$ (9,097)	$ 218	$ 9,382	$ (9,112)	$ 270

Amortization expense for intangible assets were as follows (in thousands):

	Years Ended		
	2021	2020	2019
Amortization expense	$ 34	$ 35	$ 34

Note 6 — Intangible Assets, Net (Continued)

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

Year Ended	Amount
2022	$ 32
2023	32
2024	32
2025	32
2026	32
Thereafter	58
Total	$ 218

Note 7 — Other Current Liabilities

Other current liabilities consisted of the following (in thousands):

	2021	2020
Accrued salaries and wages	$ 12,030	$ 7,074
Accrued bonuses	8,091	3,000
Accrued insurance	10	2,633
Income taxes payable	2,248	4,657
Accrued consumption tax	841	1,743
Marketing obligations	2,243	1,484
Other[1]	6,414	4,415
Total other current liabilities	$ 31,877	$ 25,006

(1) No individual item in "Other" exceeds 5% of the other current liabilities.

Note 8 — Lines of Credit

Since 1998, STAAR Japan, has had an agreement with Mizuho Bank which provides for borrowings of up to 500,000,000 Yen, at an interest rate equal to the uncollateralized overnight call rate (approximately 0.07% as of January 1, 2021) plus a 0.50% spread, and may be renewed quarterly. The credit facility is not collateralized. The Company had 142,500,000 Yen outstanding on the line of credit as of January 1, 2021 (approximately $1,379,000 based on the foreign exchange rates on January 1, 2021), which approximates fair value due to the short-term maturity and market interest rates of the line of credit. In case of default, the interest rate will be increased to 14% per annum. There was 357,500,000 Yen available for borrowing as of January 1, 2021 (approximately $3,459,000 based on the foreign exchange rates on January 1, 2021). Given its immaterial nature and the Company's existing cash resources, during the fourth quarter of 2021, the Company fully repaid and cancelled this line of credit.

In September 2013, STAAR Surgical AG, entered into a framework agreement for loans ("framework agreement") with Credit Suisse (the "Bank"). The framework agreement provides for borrowings of up to 1,000,000 CHF (Swiss Francs) (approximately $1,100,000 at the rate of exchange on January 1, 2021), to be used for working capital purposes. Accrued interest and 0.25% commissions on average outstanding borrowings is payable quarterly and the interest rate will be determined by the Bank based on the then prevailing market conditions at the time of borrowing. The framework agreement is automatically renewed on an annual basis based on the same terms assuming there is no default. The framework agreement may be terminated by either party at any time in accordance with its general terms and conditions. The framework agreement is not collateralized and contains certain conditions such as providing the Bank with audited financial statements annually and notice of significant events or conditions, as defined in the framework agreement. The Bank may also declare all amounts outstanding to be immediately due and payable upon a change of control or a "material qualification" in STAAR Surgical independent auditors' report, as defined. There were no borrowings outstanding as of January 1, 2021. Given its immaterial nature and the Company's existing cash resources, during the second quarter of 2021, the Company cancelled the framework agreement.

Note 9 — Leases

Finance Leases

The Company entered into finance leases primarily related to purchases of equipment used for manufacturing, furniture and computer-related equipment. These finance leases are two to five years in length and have fixed payment amounts for the term of the contract and have options to purchase the assets at the end of the lease term. Supplemental balance sheet information related to finance leases consisted of the following (dollars in thousands):

	2021	2020
Machinery and equipment	$ 35	$ 570
Computer equipment and software	506	806
Furniture and fixtures	475	—
Finance lease ROU assets, gross	1,016	1,376
Less accumulated depreciation	(510)	(780)
Finance lease ROU assets, net	$ 506	$ 596
Total finance lease liability	$ 509	$ 398
Weighted-average remaining lease term (in years)	3.2	0.9
Weighted-average discount rate	4.02%	3.46%

Supplemental cash flow information related to finance leases consisted of the following (in thousands):

	Years Ended		
	2021	2020	2019
Amortization of finance lease ROU asset	$ 83	$ 259	$ 584
Interest on finance lease liabilities	6	30	72
Cash paid for amounts included in the measurement of finance lease liabilities:			
Operating cash flows	6	30	72
Financing cash flows	348	561	1,294
ROU assets obtained in exchange for new finance lease liabilities	475	22	679

Operating Leases

The Company entered into operating leases primarily related to real property (office, manufacturing and warehouse facilities), automobiles and copiers. These operating leases are two to ten years in length with options to extend. The Company does not include any lease extensions in the initial valuation unless the Company was reasonably certain to extend the lease. Depending on the lease, there are those with fixed payment amounts for the entire length of the contract or payments which increase periodically as noted in the contract or increased at an inflation rate indicator. For operating leases that increase using an inflation rate indicator, the Company used the inflation rate at the time the lease was entered into for the length of the lease term.

Supplemental balance sheet information related to operating leases consisted of the following (dollars in thousands):

Note 9 — Leases (Continued)

Operating Leases (Continued)

	2021	2020
Machinery and equipment	$ 760	$ 860
Computer equipment and software	472	462
Real property	34,426	12,956
Operating lease ROU assets, gross	35,658	14,278
Less accumulated depreciation	(4,348)	(5,514)
Operating lease ROU assets, net	$ 31,310	$ 8,764
Total operating lease liability	$ 31,552	$ 9,022
Weighted-average remaining lease term (in years)	7.8	5.2
Weighted-average discount rate	3.56%	2.61%

Supplemental cash flow information related to operating leases was as follows (in thousands):

	Years Ended		
	2021	2020	2019
Operating lease cost	$ 3,345	$ 3,023	$ 2,749
Cash paid for amounts included in the measurement of operating lease liabilities:			
Operating cash flows	3,259	3,052	2,774
ROU assets obtained in exchange for new operating lease liabilities	29,269	4,938	3,495

Future Minimum Lease Commitments

Estimated future minimum lease payments under operating and finance leases having initial or remaining non-cancelable lease terms more than one year are as follows (in thousands):

Year Ended	Operating Leases	Finance Leases
2022	$ 4,993	$ 147
2023	5,422	183
2024	4,848	174
2025	3,878	42
2026	3,659	—
Thereafter	13,791	—
Total minimum lease payments, including interest	$ 36,591	$ 546
Less amounts representing interest	(5,039)	(37)
Total minimum lease payments	$ 31,552	$ 509

Note 10 — Income Taxes

Provision (Benefit) for Income Taxes

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

	Years Ended		
	2021	2020	2019
Domestic	$ (15,565)	$ (16,245)	$ (5,321)
Foreign	46,869	24,512	18,347
Income before income taxes	$ 31,304	$ 8,267	$ 13,026

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

	Years Ended		
	2021	2020	2019
Current tax provision:			
U.S. federal	$ —	$ 2	$ —
State	—	15	13
Foreign	5,308	3,186	2,446
Total current provision	5,308	3,203	2,459
Deferred tax provision (benefit):			
U.S. federal	739	(573)	(3,003)
State	106	78	(373)
Foreign	650	(354)	(105)
Total deferred provision (benefit)	1,495	(849)	(3,481)
Provision (benefit) for income taxes	$ 6,803	$ 2,354	$ (1,022)

A reconciliation of the statutory U.S. federal tax rate to the Company's effective tax rate was as follows (dollars in thousands):

	Years Ended					
	2021		2020		2019	
	Rate	Amount	Rate	Amount	Rate	Amount
Computed provision for taxes based on income at statutory rate	21.0%	$ 6,574	21.0%	$ 1,736	21.0%	$ 2,735
Increase (decrease) in taxes resulting from:						
State tax benefit	(2.5)%	(778)	(16.9)%	(1,397)	0.7%	93
Foreign tax differential	(12.4)%	(3,890)	(27.9)%	(2,304)	(11.6)%	(1,514)
Expiration of state net operating tax loss carryforwards	1.1%	330	3.2%	268	8.0%	1,039
ASC 718 share based payment adjustment	4.6%	1,440	5.8%	476	—	—
Incentive stock option compensation	(7.5)%	(2,346)	(59.4)%	(4,907)	(0.4)%	(55)
Non-qualified stock option and restricted stock tax deduction in excess of cumulative book deduction	(45.7)%	(14,315)	(52.3)%	(4,324)	(12.9)%	(1,679)
Executive compensation Section 162(m) limitation	33.9%	10,608	43.0%	3,552	4.4%	569
GILTI inclusion	0.5%	171	54.0%	4,461	25.9%	3,372
Other	(0.9)%	(293)	(1.3)%	(106)	(0.9)%	(110)
Valuation allowance	29.7%	9,302	59.3%	4,899	(42.0)%	(5,472)
Effective tax provision (benefit)	21.7%	$ 6,803	28.5%	$ 2,354	(7.8)%	$ (1,022)

Note 10 — Income Taxes (Continued)

Provision (Benefit) for Income Taxes (Continued)

The Company recorded income tax expense during the year ended 2021 due to income tax expense generated from pre-tax profits in its foreign jurisdictions and a recapture of its U.S. valuation allowance of $845,000, as a result of increased tax deductions in the projection of taxable income used in its valuation assessment. From time to time, the Company may adjust the projections of taxable income as a result of current conditions. The Company recorded income tax expense during the year ended 2020 due income tax expense generated from pre-tax profits in its foreign jurisdictions and a release of $495,000 of its U.S. valuation allowance, as a result of increases in foreign income and changes in the usage and release of its deferred tax assets. The Company recorded an income tax benefit during the year ended 2019 due to the income tax benefit from the release of the U.S. valuation allowance of $3,376,000, as a result of positive evidence in U.S. projected future profits (see Note 1 – Income Taxes), offset by income tax expense generated from pre-tax profits in its foreign operations.

All earnings from the Company's subsidiaries are not considered to be permanently reinvested. The Company formed STAAR Surgical UK Limited ("STAAR UK") as a holding company in the United Kingdom ("U.K.") for its foreign subsidiaries. Based on the current tax treaties there is no withholding on distributions between Switzerland and the U.K. and the U.K. and the U.S., therefore, there were no withholding taxes paid to foreign jurisdictions for 2021, 2020 and 2019.

For 2021, 2020 and 2019, in accordance with the 2017 Tax Act, the Company included GILTI of $800,000, $21,200,000 and $15,100,000, respectively, in U.S. gross income, which was fully offset with current losses and net operating loss carryforwards. The Company utilized the high-tax exception to exclude income from foreign jurisdictions with foreign taxes at an effective rate that is higher than 90 percent of the applicable highest U.S. corporate tax rate. The Company was not able to utilize the deduction of 50 percent of GILTI, as this deduction is limited by the Company's pre-GILTI U.S. tax income.

Deferred Tax Assets and Liabilities

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes.

Significant components of the Company's deferred tax assets (liabilities) were as follows (in thousands):
Note 10 — Income Taxes (Continued)

Deferred Tax Assets and Liabilities (Continued)

	2021	2020
Deferred tax assets:		
Allowance for doubtful accounts and sales returns	$ 195	$ 357
Inventories	444	691
Accrued vacation	581	599
Accrued other expenses	1,869	786
Stock-based compensation	2,146	3,277
Pensions	824	1,679
Net operating loss carryforwards	48,223	38,642
Business, foreign, AMT and R&D credit carryforwards	3,100	3,051
Prepaid expenses	272	280
Capitalized R&D	880	1,000
Operating lease liability	6,894	1,687
Other	67	19
Valuation allowance	(51,794)	(42,502)
Total deferred tax assets	$ 13,701	$ 9,566
Deferred tax liabilities:		
Foreign tax withholding	$ (1,295)	$ (1,295)
Operating lease ROU assets	(6,862)	(1,662)
Depreciation and amortization	(888)	(424)
Amortization of R&D	(763)	(846)
Net foreign earnings not permanently reinvested	(891)	(617)
Total deferred tax liabilities	(10,699)	(4,844)
Total net deferred tax assets	$ 3,002	$ 4,722

The Company's net deferred tax assets (liabilities) by jurisdiction were as follows (in thousands):

	2021	2020
Federal deferred tax assets	$ 2,838	$ 3,576
State deferred tax assets	188	295
Japan deferred tax assets	787	1,073
Switzerland deferred tax liabilities(1)	(811)	(222)
Total net deferred tax assets	$ 3,002	$ 4,722

(1) Includes $1,295,000 of pre-2019 withholding taxes on unremitted foreign earnings

The Company had accrued net income taxes payable of $2,221,000 and $4,650,000 at December 31, 2021 and January 1, 2021, respectively, primarily due to taxes owed in foreign jurisdictions.

Note 10 — Income Taxes (Continued)

U.S. Jurisdiction

The ultimate realization of deferred tax assets is dependent upon future generation of income during the periods in which temporary differences representing net future deductible amounts become deductible. Management considers the projected future income and tax planning strategies in making this assessment. In addition, management considers all other available positive and negative evidence in its analysis. This includes existing profits in foreign jurisdiction as well as projected future profits.

Under the incremental cash tax savings approach, the valuation allowance release (recapture) was as follows (in thousands):

	Years Ended		
	2021	2020	2019
Federal	$ (739)	$ 573	$ 3,003
State	(106)	(78)	373
Valuation allowance release (recapture)	$ (845)	$ 495	$ 3,376

Under the incremental cash tax savings approach, the valuation allowances remain as the usage of the remaining net operating losses and deferred tax assets will not result in cash tax savings and therefore provide no additional benefit were as follows (in thousands):

	2021	2020
Cumulative federal valuation allowance	$ 43,626	$ 34,681
Cumulative state valuation allowance	7,848	7,399
Total U.S. valuation allowance	$ 51,474	$ 42,080

As of December 31, 2021, the Company had federal net operating loss carryforwards of $194,710,000 available to reduce future income taxes of its U.S. operations. The pre-2018 federal net operating loss carryforwards expire in varying amounts between 2022 and 2037. The post-2017 federal net operating loss carryforwards can be carried forward indefinitely based on the enacted legislation from the 2017 Tax Act. In California, the main state from which the Company conducts its domestic operations, the Company has state net operating losses of $46,109,000 available to reduce future California income taxes. In 2020, California enacted Assembly Bill 85 which imposed limits on the usability of California state net operating losses and research and development credits in tax years beginning after 2019 and before 2023. The California net operating loss carryforwards expire in varying amounts between 2028 and 2040.

Further, pursuant to the provisions of Internal Revenue Code Section 382, significant changes in ownership may restrict the future utilization of these tax loss carry forwards. For 2021 the Company does not have a change in ownership.

Foreign Jurisdictions

STAAR Surgical AG

Due to STAAR Surgical AG's history of profits, its deferred tax assets are considered fully realizable. The Swiss government has approved a tax holiday for STAAR Surgical AG providing a 10.45% income tax rate for 2020 through 2024, and a 10.90% income tax rate for 2025 through 2029.

STAAR Japan

Since 2012, STAAR Japan functions as a limited-risk distributor with a guaranteed return from STAAR Surgical AG and accordingly, STAAR Japan's deferred tax assets are considered fully realizable. STAAR Japan's net deferred tax assets included a valuation allowance of $41,000 and $35,000 as of December 31, 2021 and January 1, 2021, respectively, related to non-deductible stock compensation for directors. STAAR Japan is subject to the statutory corporate income tax rate of 25.59%.

Note 10 — Income Taxes (Continued)

The following tax years remain subject to examination:

Significant jurisdictions	Open Years
U.S. Federal	2018 – 2020
California	2017 – 2020
Switzerland	2020
Japan	2019 – 2020

Note 11 – Employee Benefit Plans

Defined Benefit Plan – Switzerland

The Company maintains a passive pension plan (the "Swiss Plan") covering employees of STAAR Surgical AG, which is accounted for as a defined benefit plan.

In Switzerland employers are required to provide a minimum pension plan for their staff. Contributions of both the employees and employer finance the Swiss Plan. The amount of the contributions is defined by the plan regulations and cannot be decreased without amending the plan regulations. It is required that the employer contribute an amount equal to or greater than the employee contribution.

The following table shows the changes in the benefit obligation and plan assets and the Swiss Plan's funded status (in thousands):

	2021	2020
Change in Projected Benefit Obligation:		
Projected benefit obligation, beginning of period	$ 25,470	$ 12,864
Service cost	1,089	1,139
Interest cost	55	51
Participant contributions	678	579
Benefits deposited (paid)	2,147	6,299
Actuarial (gain) loss	(1,875)	4,620
Prior service credit	(1,317)	(82)
Projected benefit obligation, end of period	$ 26,247	$ 25,470
Change in Plan Assets:		
Plan assets at fair value, beginning of period	$ 15,551	$ 6,774
Actual return on plan assets (including foreign currency impact)	(374)	1,195
Employer contributions	807	704
Participant contributions	678	579
Benefits deposited (paid)	2,147	6,299
Plan assets at fair value, end of period	$ 18,809	$ 15,551
Funded status (pension liability), end of year[1]	$ (7,438)	$ (9,919)
Amount Recognized in Accumulated Other Comprehensive Income (Loss), net of tax:		
Actuarial loss on plan assets	$ (922)	$ (198)
Actuarial loss on benefit obligation	(6,782)	(8,453)
Actuarial gain recognized in current year	1,499	1,029
Prior service credit	1,443	301
Effect of curtailments	610	610
Accumulated other comprehensive loss	$ (4,152)	$ (6,711)
Accumulated benefit obligation at year end	$ (25,179)	$ (24,291)

(1) The underfunded balance was included in pension liability on the Consolidated Balance Sheets.

Note 11 – Employee Benefit Plans (Continued)

Defined Benefit Plan – Switzerland (Continued)

Net periodic pension cost associated with the Swiss Plan included the following components (in thousands):

	Years Ended		
	2021	2020	2019
Service cost(1)	$ 1,089	$ 1,139	$ 739
Interest cost(2)	55	51	77
Expected return on plan assets(2)	(434)	(264)	(147)
Prior service credit(2),(3)	(42)	(34)	(21)
Actuarial loss recognized in current period(2),(3)	524	318	129
Net periodic pension cost	$ 1,192	$ 1,210	$ 777

(1) Recognized in selling general and administrative expenses on the Consolidated Statements of Income.
(2) Recognized in other income (expense), net, on the Consolidated Statements of Income.
(3) Amounts reclassified from accumulated other comprehensive income (loss).

Changes in other comprehensive income (loss), net of tax, associated with the Swiss Plan included the following components (in thousands):

	Years Ended		
	2021	2020	2019
Current year actuarial gain (loss) on plan assets	$ (724)	$ 833	$ 4
Current year actuarial gain (loss) on benefit obligation	1,671	(4,136)	(2,172)
Actuarial gain recorded in current year	470	285	114
Prior service credit	1,142	43	93
Effect of curtailments	—	1	—
Change in other comprehensive gain (loss)	$ 2,559	$ (2,974)	$ (1,961)

Net periodic pension cost and projected and accumulated pension obligation for the Company's Swiss Plan were calculated using the following assumptions:

	2021	2020
Discount rate	0.3%	0.2%
Salary increases	2.0%	2.0%
Expected return on plan assets	2.5%	2.5%
Expected average remaining working lives in years	9.3	10.1

The discount rates are based on an assumed duration of the pension obligations and estimated using the rates of returns for AAA and AA-rated Swiss and foreign CHF-denominated corporate bonds listed on the SIX Swiss Exchange. The salary increase rate was based on the Company's best estimate of future increases over time. The expected long-term rate of return on plan assets is based on the expected asset allocation and assumptions concerning long-term interest rates, inflation rates, and risk premiums for equities above the risk-free rates of return. These assumptions take into consideration historical long-term rates of return for relevant asset categories.

Under Swiss law, pension funds are legally independent from the employer and all the contributions are invested with regulated entities. The Company has a contract with Allianz Suisse Life Insurance Company's BVG Collective Foundation (the "Foundation") to manage its Swiss pension fund. Multiple employers contract with the Foundation to manage the employers' respective pension plans. The Foundation manages the pension plans of its contracted employers as a collective entity. The investment strategy is determined by the Foundation and applies to all members of the collective Foundation. There are no separate financial statements for each employer contract. The pension plan assets of all the employers that contract with the Foundation are comingled. They are considered multiple-employer plans under ASC 715-30-35-70 and therefore accounted for as single-employer plans.

Note 11 – Employee Benefit Plans (Continued)

Defined Benefit Plan – Switzerland (Continued)

As there are no separate financial statements for each employer contract, there are no individual investments that can be directly attributed to the Company's pension plan assets. However, the funds contributed by an employer are specifically earmarked for its employees and the total assets of the plan allocable to Company's employees are separately tracked by the Foundation. The lack of visibility into the specific investments of the plan assets and how they are valued is a significant unobservable input, therefore, the Company considers the plan assets collectively to be Level 3 assets under the fair value hierarchy (see Note 1).

The table below sets forth the fair value of Plan assets at January 1, 2021 and December 31, 2021, and the related activity in years ended 2021 and 2020, in accordance with ASC 715-20-50-1(d) (in thousands):

	Insurance Contracts (Level 3)
Ending balance at January 3, 2020	$ 6,774
Actual return on plan assets	1,195
Purchases, sales, and settlement	7,582
Ending balance at January 1, 2021	$ 15,551
Actual return on plan assets	(374)
Purchases, sales, and settlement	3,632
Ending balance at December 31, 2021	$ 18,809

During fiscal year 2022, the Company expects to make cash contributions totaling approximately $853,000 to the Swiss Plan.

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

Year Ended	Amount
2022	$ 80
2023	117
2024	133
2025	151
2026	172
Thereafter	6,785
Total	$ 7,438

Defined Benefit Plan-Japan

STAAR Japan maintains a noncontributory defined benefit pension plan ("Japan Plan") substantially covering all the employees of STAAR Japan. Benefits under the Japan Plan are earned, vested, and accumulated based on a point-system, primarily based on the combination of years of service, actual and expected future grades (management or non-management) and actual and future zone (performance) levels of the employees. Each point earned is worth a fixed monetary value, 1,000 Yen per point, regardless of the level grade or zone of the employee. Gross benefits are calculated based on the cumulative number of points earned over the service period multiplied by 1,000 Yen. The mandatory retirement age limit is 60 years old.

STAAR Japan administers the pension plan and funds the obligations of the Japan Plan from STAAR Japan's operating cash flows. STAAR Japan is not required, and does not intend, to provide contributions to the Plan to meet benefit obligations and therefore does not have any plan assets. Benefit payments are made to beneficiaries as they become due.

Note 11 – Employee Benefit Plans (Continued)

Defined Benefit Plan-Japan (Continued)

The funded status of the benefit plan was as follows (in thousands):

	2021	2020
Change in Projected Benefit Obligation:		
Projected benefit obligation, beginning of period	$ 2,021	$ 1,750
Service cost	177	180
Interest cost	6	5
Actuarial (gain) loss	(276)	34
Benefits paid	(425)	(35)
Foreign exchange adjustment	(183)	87
Projected benefit obligation, end of period	$ 1,320	$ 2,021
Change in Plan Assets:		
Plan assets at fair value, beginning of period	$ —	$ —
Actual return on plan assets	—	—
Employer contributions	—	—
Benefits paid	—	—
Distribution of plan assets	—	—
Foreign exchange adjustment	—	—
Plan assets at fair value, end of period	$ —	$ —
Funded status (pension liability), end of year[1]	$ (1,320)	$ (2,021)
Amount Recognized in Accumulated Other Comprehensive Income (Loss), net of tax:		
Actuarial loss	$ (35)	$ (38)
Prior service cost	6	7
Net gain	221	46
Accumulated other comprehensive income	$ 192	$ 15
Accumulated benefit obligation at year end	$ (1,280)	$ (1,858)

(1) The underfunded balance was included in pension liability on the Consolidated Balance Sheets.

Net periodic pension cost associated with the Japan Plan included the following components (in thousands):

	Years Ended		
	2021	2020	2019
Service cost[1]	$ 177	$ 180	$ 185
Interest cost[2]	6	5	7
Prior service credit[2],[3]	5	(1)	(1)
Net periodic pension cost	$ 188	$ 184	$ 191

(1) Recognized in selling general and administrative expenses on the Consolidated Statements of Income.
(2) Recognized in other income (expense), net, on the Consolidated Statements of Income.
(3) Amounts reclassified from accumulated other comprehensive loss.

Note 11 – Employee Benefit Plans (Continued)

Defined Benefit Plan-Japan (Continued)

Changes in other comprehensive income (loss), net of tax, associated with the Japan Plan include the following components (in thousands):

	Years Ended		
	2021	2020	2019
Amortization of actuarial loss	$ 3	$ (1)	$ (1)
Prior service cost	(1)	—	(1)
Actuarial income (loss) recorded in current year	175	(22)	30
Change in other comprehensive income (loss)	$ 177	$ (23)	$ 28

Net periodic pension cost and projected and accumulated pension obligation for the Company's Japan Plan were calculated using the following assumptions:

	2021	2020
Discount rate	0.2%	0.3%
Salary increases	1.8%	4.4%
Expected return on plan assets	N/A	N/A
Expected average remaining working lives in years	9.7	10.7

The discount rates are based on the yield curve of corporate bonds rated AA or higher. The salary increase average rate was based on the Company's best estimate of future increases over time.

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

Year Ended	Amount
2022	$ 89
2023	96
2024	138
2025	211
2026	103
Thereafter	683
Total	$ 1,320

Defined Contribution Plan

The Company has a 401(k) profit sharing plan ("401(k) Plan") for the benefit of qualified employees in the U.S. During the year ended December 31, 2021 employees who participate may elect to make salary deferral contributions to the 401(k) Plan up to $19,500 of the employees' eligible payroll subject to annual Internal Revenue Code maximum limitations (with a $6,500 annual catch-up contribution permitted for those over 50 years old). The Company's contribution percentage is 80% of the employee's contribution up to the first 6% of the employee's compensation. In addition, STAAR may make a discretionary contribution to qualified employees, in accordance with the 401(k) Plan. The Company's contributions, net of forfeitures, to the 401(k) Plan were as follows (in thousands):

	Years Ended		
	2021	2020	2019
Employer contributions, net of forfeitures	$ 1,563	$ 1,281	$ 1,279

Note 12 — Stockholders' Equity

Incentive Plan

The Amended and Restated Omnibus Equity Incentive Plan ("the Plan") provides for various forms of stock-based incentives. To date, of the available forms of awards under the Plan, the Company has granted only stock options, restricted stock, unrestricted share grants, RSUs and PSUs. Options under the Plan are granted at fair market value on the date of grant, become exercisable generally over a three-year period, or as determined by the Board of Directors, and expire over periods not exceeding 10 years from the date of grant. Certain option and share awards provide for accelerated vesting if there is a change in control and pre-established financial metrics are met (as defined in the Plan). Grants of restricted stock outstanding under the Plan generally vest over periods of one to three years. Grants of RSUs and PSUs outstanding under the Plan generally vest based on service, performance, or a combination of both. On July 30, 2020, stockholders approved a proposal to increase the number of shares under the Plan by 2,650,000 shares, for a total of 18,035,000 shares. As of December 31, 2021, there were 3,020,430 shares available for grant under the Plan.

Stock-Based Compensation

The Company recognized a net income tax benefit in the Consolidated Statements of Income for stock-based compensation expense for incentive stock options and non-qualified stock options, as a result of disqualifying dispositions and exercises, respectively. The Company does not recognize deferred income taxes for incentive stock option compensation expense, and records a tax deduction only when a disqualified disposition has occurred (see Note 10).

The following table represents the fair value of stock-based compensation granted during the year ended 2021 (in thousands):

	Fair Value
Stock options	$ 12,309
RSUs	6,661
Restricted stock	466
Total stock-based compensation expense	$ 19,436

The Company recorded stock-based compensation expense by award as follows (in thousands):

	Years Ended		
	2021	2020	2019
Employee stock option	$ 10,373	$ 9,577	$ 8,144
Restricted stock	616	428	320
RSUs	2,667	1,732	1,905
PSUs	371	147	—
Nonemployee stock options	578	262	178
Total stock-based compensation expense	$ 14,605	$ 12,146	$ 10,547

The Company recorded stock-based compensation expense in the following categories (in thousands):

	Years Ended		
	2021	2020	2019
Cost of sales	$ 215	$ 112	$ 52
General and administrative	6,495	4,925	4,010
Selling and marketing	3,454	3,471	3,318
Research and development	4,441	3,638	3,167
Total stock-based compensation expense, net	14,605	12,146	10,547
Amounts capitalized as part of inventory	1,295	1,129	1,017
Total stock-based compensation expense, gross	$ 15,900	$ 13,275	$ 11,564

Note 12 — Stockholders' Equity (Continued)

Stock-Based Compensation (Continued)

As of December 31, 2021, total unrecognized compensation cost related to non-vested stock-based compensation arrangements granted under the Plan were as follows (in thousands):

	2021
Stock options	$ 12,682
Restricted stock, RSUs and PSUs	6,981
Total unrecognized stock-based compensation cost	$ 19,663

This cost is expected to be recognized over a weighted-average period of approximately one and a half years.

Assumptions

The fair value of each option award is estimated on the date of grant using a Black-Scholes option valuation model applying the weighted-average assumptions noted in the following table. Expected volatilities are based on historical volatility of the Company's stock. The expected term of options granted is derived from the historical exercises and post-vesting cancellations, and represents the period of time that options granted are expected to be outstanding. The Company has calculated a 6% estimated forfeiture rate based on historical forfeiture experience. The risk-free rate is based on the U.S. Treasury yield curve corresponding to the expected term at the time of the grant.

	Years Ended		
	2021	2020	2019
Expected dividend yield	0%	0%	0%
Expected volatility	53%	53%	53%
Risk-free interest rate	0.84%	0.53%	2.40%
Expected term (in years)	5.38	5.72	5.66

Stock Options

A summary of option activity under the Plan for the year ended December 31, 2021 was as follows:

	Shares (in 000's)	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (years)	Aggregate Intrinsic Value (in 000's)
Outstanding at January 1, 2021	3,418	$ 19.80		
Granted	273	95.32		
Exercised	(1,206)	16.12		
Forfeited or expired	(50)	33.77		
Outstanding at December 31, 2021	2,435	$ 29.81	6.34	$ 151,033
Exercisable at December 31, 2021	1,863	$ 20.54	5.75	$ 131,837

Note 12 — Stockholders' Equity (Continued)

Stock Options (Continued)

A summary of unvested options activity under the Plan for the year ended December 31, 2021 was as follows:

	Shares (in 000's)	Weighted-Average Grant-Date Fair Value
Unvested at January 1, 2021	1,046	$ 15.09
Granted	273	45.08
Forfeited or expired	(50)	7.89
Vested	(697)	15.74
Unvested at December 31, 2021	572	$ 28.63

The weighted average grant date fair value of options granted and the total intrinsic value of options exercised were as follows:

	Years Ended		
	2021	2020	2019
Weighted-average grant-date fair value	$ 45.08	$ 13.85	$ 17.95
Intrinsic value of options (in thousands)	$ 127,024	$ 59,771	$ 9,955

Restricted Stock, Restricted Stock Units and Performance Stock Units

A summary of restricted stock, RSU and PSU activity under the Plan for the year ended December 31, 2021 was as follows:

	Restricted Stock		Restricted Stock Units		Performance Stock Units	
	Units (in 000's)	Weighted-Average Grant-Date Fair Value	Units (in 000's)	Weighted-Average Grant-Date Fair Value	Units (in 000's)	Weighted-Average Grant-Date Fair Value
Outstanding at January 1, 2021	11	$ 59.06	122	$ 32.97	15	$ 51.42
Granted	3	148.36	63	105.62	—	—
Vested	(11)	59.95	(54)	35.34	(5)	51.42
Outstanding at December 31, 2021	3	$ 154.96	131	$ 66.94	10	$ 51.42

Note 13 — Commitments and Contingencies

Asset Retirement Obligation

The Company recorded certain Asset Retirement Obligations ("ARO"), in accordance with ASC 410-20 in connection with the Company's obligation to return its Japan facility to its "original condition", as defined in the lease agreement. The Company has recorded approximately $198,000 and $221,000, representing the fair value of the ARO liability obligation in noncurrent liabilities at December 31, 2021 and January 1, 2021, respectively. This lease expires in 2023.

Open Purchase Orders and Severance Payable

As of December 31, 2021, there were open purchase orders of $17,342,000 and severance payable of $90,000.

Note 13 — Commitments and Contingencies (Continued)

Indemnification Agreements

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

Tax Filings

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

Employment Agreements

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

Litigation and Claims

From time to time, the Company is involved in various legal proceedings and other matters arising in the normal course of business. These legal proceedings and other matters may relate to, among other things, contractual rights and obligations, employment matters, or claims of product liability. STAAR maintains insurance coverage for various matters, including product liability and certain securities claims. While the Company does not believe that any of the claims known is likely to have a material adverse effect on the Company's financial condition or results of operations, new claims or unexpected results of existing claims could lead to significant financial harm.

Note 14 — Related Party Transactions

The Company has made various advances to certain non-executive employees. Amounts due from employees are included in prepayments, deposits, and other current assets were as follows (in thousands):

	2021	2020
Due from employees	$ 49	$ 5

Note 15 — Supplemental Disclosure of Cash Flow Information

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

	Years Ended		
	2021	2020	2019
Non-cash investing and financing activities:			
ROU assets obtained in exchange for new finance lease liabilities	$ 475	$ 22	$ 679
Purchase of property and equipment included in accounts payable	$ 1,331	$ 523	$ 381
Cash paid:			
Interest	$ 75	$ 64	$ 105
Taxes	$ 7,466	$ 1,336	$ 792

Note 16 — Basic and Diluted Net Income Per Share

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

	Years Ended		
	2021	2020	2019
Numerator:			
Net income	$ 24,501	$ 5,913	$ 14,048
Denominator:			
Weighted average common shares:			
Common shares outstanding	47,213	45,616	44,504
Less: Unvested restricted stock	(3)	(11)	(11)
Denominator for basic calculation	47,210	45,605	44,493
Weighted average effects of potentially diluted common stock:			
Stock options	2,145	2,272	2,254
Unvested restricted stock	5	4	6
RSUs	86	71	142
PSUs	10	1	—
Denominator for diluted calculation	49,456	47,953	46,895
Net income per share:			
Basic	$ 0.52	$ 0.13	$ 0.32
Diluted	$ 0.50	$ 0.12	$ 0.30

The following table sets forth (in thousands) the weighted average number of options to purchase shares of common stock, restricted stock, RSUs and PSUs with either exercise prices or unrecognized compensation cost per share greater than the average market price per share of the Company's common stock, which were not included in the calculation of diluted per share amounts because the effects would be anti-dilutive.

	Years Ended		
	2021	2020	2019
Stock options	228	20	1,503
Restricted stock, RSUs and PSUs	6	—	—
Total	234	20	1,503

Note 17 — Disaggregation of Revenues, Geographic Sales and Product Sales

In the following tables, revenues are disaggregated by category, sales by geographic market and sales by product data. The following breaks down revenues into the following categories (in thousands):

	Years Ended		
	2021	2020	2019
Non-consignment sales	$ 210,517	$ 137,369	$ 132,716
Consignment sales	19,955	26,091	17,469
Total net sales	$ 230,472	$ 163,460	$ 150,185

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

	Years Ended		
	2021	2020	2019
Domestic	$ 10,095	$ 6,158	$ 8,106
Foreign:			
China[1]	107,333	71,692	64,820
Japan	40,973	34,986	26,881
Other[2]	72,071	50,624	50,378
Total foreign sales	220,377	157,302	142,079
Total net sales	$ 230,472	$ 163,460	$ 150,185

(1) The China region includes sales into China and Hong Kong.
(2) No other location individually exceeds 10% of the total net sales.

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

	Years Ended		
	2021	2020	2019
ICLs	$ 212,905	$ 141,407	$ 129,322
Other product sales			
Cataract IOLs	12,519	13,574	15,689
Other surgical products	5,048	8,479	5,174
Total other product sales	17,567	22,053	20,863
Total net sales	$ 230,472	$ 163,460	$ 150,185

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

Note 18 —Geographic Assets

The composition of the Company's long-lived assets between those in the U.S., Japan and Switzerland was as follows (in thousands):

	2021			
	U.S.	Japan	Switzerland	Total
Property, plant and equipment, net	$ 27,859	$ 365	$ 7,688	$ 35,912
Finance lease ROU assets, net	475	31	—	506
Operating lease ROU assets, net	24,564	736	6,010	31,310
Intangible assets, net	83	135	—	218
Total	$ 52,981	$ 1,267	$ 13,698	$ 67,946

	2020			
	U.S.	Japan	Switzerland	Total
Property, plant and equipment, net	$ 19,289	$ 420	$ 4,321	$ 24,030
Finance lease ROU assets, net	527	69	—	596
Operating lease ROU assets, net	4,380	530	3,854	8,764
Intangible assets, net	83	187	—	270
Total	$ 24,279	$ 1,206	$ 8,175	$ 33,660

Note 19 — Quarterly Financial Data (Unaudited)

Summary unaudited quarterly financial data from continuing operations for years ended 2021 and 2020 was as follows (in thousands except per share data). The Company has derived this data from the unaudited consolidated interim financial statements that, in the Company's opinion, have been prepared on substantially the same basis as the audited financial statements contained elsewhere in this report and include all normal recurring adjustments necessary for a fair presentation of the financial information for the periods presented. These unaudited quarterly results should be read in conjunction with the financial statements and notes thereto included elsewhere in this report. The operating results in any quarter are not necessarily indicative of the results that may be expected for any future period.

December 31, 2021	1st Quarter	2nd Quarter	3rd Quarter	4th Quarter
Net sales	$ 50,752	$ 62,367	$ 58,352	$ 59,001
Gross profit	39,142	49,203	45,301	44,991
Net income	4,992	8,567	6,020	4,922
Net income per share – basic	0.11	0.18	0.13	0.10
Net income per share – diluted	0.10	0.17	0.12	0.10

January 1, 2021	1st Quarter	2nd Quarter	3rd Quarter	4th Quarter
Net sales	$ 35,187	$ 35,194	$ 47,081	$ 45,998
Gross profit	24,760	24,430	34,871	34,301
Net income (loss)	(134)	(1,172)	3,892	3,327
Net income (loss) per share – basic	—	(0.03)	0.08	0.07
Net income (loss) per share – diluted	—	(0.03)	0.08	0.07

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

Note 20 – Reclassifications

Certain amounts in previously issued financial statements related to accounts payable and other current liabilities have been reclassified to conform to fiscal 2021 presentation.

Note 21 – COVID-19 Developments

In December 2019, COVID-19 surfaced and in March 2020, the World Health Organization declared a pandemic related to the rapid spread of COVID-19 around the world. The impact of the COVID-19 outbreak on the businesses and the economy in the U.S. and the rest of the world is, and is expected to continue to be, uncertain and may continue to be significant. Accordingly, the Company cannot predict the extent to which its financial condition and results of operation will be affected. On March 17, 2020, the Company suspended most of its production and non-essential business locations where employees can work from home. A very limited number of manufacturing personnel remained at work for critical late staged processes, until the end of March 2020. Manufacturing resumed on April 27, 2020. The Company's revenues have been adversely impacted, and the Company experienced a substantial slowdown in sales beginning March 20, 2020 in global geographies characterized as "hot spots" for the COVID-19 virus, including parts of Europe, North America, Asia, the Middle East and India. In certain of these markets, sales have paused as elective surgeries are discouraged to support COVID-19 related needs. The Company continues to monitor the commercial and operational impact of new variants of COVID-19 in its markets.

STAAR SURGICAL COMPANY AND SUBSDIARIES

SCHEDULE II — VALUATION AND QUALIFYING ACCOUNTS AND RESERVES

Column A	Column B	Column C - Additions		Column D	Column E
Description	Balance at Beginning of Year	Charged to costs and expenses	Charged to other accounts	Deductions	Balance at End of Year
			(in thousands)		
2021					
Allowance for doubtful accounts	$ 59	$ 5	$ —	$ 21	$ 43
Sales return reserve	4,532	14,159	—	13,875	4,816
Deferred tax asset valuation allowance	42,502	9,591	—	299	51,794
	$ 47,093	$ 23,755	$ —	$ 14,195	$ 56,653
2020					
Allowance for doubtful accounts	$ 88	$ 115	$ —	$ 144	$ 59
Sales return reserve	3,644	9,307	—	8,419	4,532
Deferred tax asset valuation allowance	37,007	5,747	—	252	42,502
	$ 40,739	$ 15,169	$ —	$ 8,815	$ 47,093
2019					
Allowance for doubtful accounts	$ 550	$ (320)	$ —	$ 142	$ 88
Sales return reserve	2,895	6,514	—	5,765	3,644
Deferred tax asset valuation allowance	43,075	(5,124)	—	944	37,007
	$ 46,520	$ 1,070	$ —	$ 6,851	$ 40,739

Exhibit 21.1

Subsidiaries of STAAR Surgical Company

Name of Subsidiary	Other Names Under Which it Does Business	State or Other Jurisdiction of Incorporation
STAAR Surgical UK LTD	None	United Kingdom
STAAR Surgical AG	None	Switzerland
STAAR Japan Inc.	STAAR Japan Godo Kaisha	Japan
STAAR Surgical PTE. LTD	None	Singapore
STAAR Optical Equipment Technology (Shanghai) Co., LTD	None	China
STAAR Surgical CHINA CO., LTD	None	China
STAAR Surgical India Private Limited	None	India

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

STAAR Surgical Company
Lake Forest, California

We hereby consent to the incorporation by reference in the Registration Statements on Form S-3 (No. 333-148902, No. 333-143131, No. 333-124022, No. 333-116901 and No. 333-238043) and Form S-8 (No. 333-228138, No. 333-213046, No. 333-201232, No. 333-111154 No. 333-240332, and No. 333-189349) of STAAR Surgical Company of our reports dated February 23, 2022, relating to the consolidated financial statements and financial statement schedule, and the effectiveness of STAAR Surgical Company's internal control over financial reporting, which appear in this Annual Report on Form 10-K.

/s/ BDO USA, LLP

Los Angeles, California
February 23, 2022

Exhibit 31.1

CERTIFICATIONS

I, Caren Mason certify that:

1. I have reviewed this annual report on Form 10-K of STAAR Surgical Company;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: February 23, 2022

/s/ CAREN MASON

Caren Mason

President, Chief Executive Officer, and Director (principal executive officer)

Exhibit 31.2

CERTIFICATIONS

I, Patrick F. Williams, certify that:

1. I have reviewed this annual report on Form 10-K of STAAR Surgical Company;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting

Dated: February 23, 2022

/s/ PATRICK F. WILLIAMS

Patrick F. Williams
Chief Financial Officer
(principal financial officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the filing of the Annual Report on Form 10-K for the year ended December 31, 2021 (the "Report") by STAAR Surgical Company ("the Company"), each of the undersigned hereby certifies that:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company as of and for the periods presented in the Report.

Dated:February 23, 2022

/s/ CAREN MASON

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

Dated: February 23, 2022

/s/ PATRICK F. WILLIAMS

Patrick F. Williams
Chief Financial Officer
(principal financial officer)

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