

STAAR SURGICAL CO
Form 10-K
March 08, 2012

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 30, 2011

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 (I.R.S. Employer
incorporation or organization) Identification No.)*

1911 Walker Avenue 91016

Monrovia, California

(Address of principal executive offices)

(626) 303-7902

(Registrant's telephone number, including area code)

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

Edgar Filing: STAAR SURGICAL CO - Form 10-K

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

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

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

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

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

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

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

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

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

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant as of July 1, 2011, the last business day of the registrant's most recently completed second fiscal quarter, was approximately \$152,678,000 based on the closing price per share of \$5.32 of the registrant's Common Stock on that date.

The number of shares outstanding of the registrant's Common Stock as of March 2, 2012 was 36,201,051.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement relating to its 2012 annual meeting of stockholders, which will be filed with the Securities and Exchange Commission pursuant to Regulation 14A within 120 days of the close of the registrant's last fiscal year, are incorporated by reference into Part III of this report.

STAAR SURGICAL COMPANY

TABLE OF CONTENTS

	Page
PART 1	
ITEM 1. BUSINESS	2
ITEM 1A. RISK FACTORS	18
ITEM 1B. UNRESOLVED STAFF COMMENTS	25
ITEM 2. PROPERTIES	25
ITEM 3. LEGAL PROCEEDINGS	25
Item 4. Mine Safety Disclosure	25
PART II	
ITEM 5. MARKET FOR REGISTRANT’S COMMON EQUITY, RELATED STOCKHOLDER MATTERS, AND ISSUER PURCHASES OF EQUITY SECURITIES	26
ITEM 6. SELECTED FINANCIAL DATA	28
ITEM 7. MANAGEMENT’S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS	29
ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK	43
ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA	44
ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE	44
ITEM 9A. CONTROLS AND PROCEDURES	44
ITEM 9B. OTHER INFORMATION	45
PART III	
ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE	47
ITEM 11. EXECUTIVE COMPENSATION	47
ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS	47
ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS AND DIRECTOR INDEPENDENCE	47
ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES	47
PART IV	

**ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES
SIGNATURES**

48

1

PART I

This Annual Report on Form 10-K contains statements that constitute “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. These statements include comments regarding the intent, belief or current expectations of the Company and its management. Readers can recognize forward-looking statements by the use of words like “anticipate,” “estimate,” “expect,” “project,” “intend,” “plan,” “believe,” “will,” “target,” “forecast” and similar expressions in connection with any of future operating or financial performance. STAAR Surgical Company cautions investors and prospective investors that any such forward-looking statements are not guarantees of future performance and involve risks and uncertainties, and that actual results may differ materially from those projected in the forward-looking statements. See “Item 1A. Risk Factors.”

Item 1. Business

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

Refractive surgery corrects the types of visual disorders that glasses or contact lenses have traditionally treated. 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, 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 surgeon removes the eye’s natural lens and replaces it with an artificial lens called an intraocular lens (IOL) to restore the patient’s vision.

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

STAAR®, Visian®, Collamer®, nanoFLEX™, nanoPOINT™, Epiphany™, and AquaFlow™ are trademarks or registered trademarks of STAAR in the U.S. and other countries. Collamer® is the brand name for STAAR’s proprietary collagen

copolymer lens material.

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

Operations

STAAR has significant operations globally. Activities outside the U.S. accounted for 78% of our total sales in fiscal year 2011. STAAR sells its products in approximately 60 countries, with direct distribution in North America and Japan and independent distribution in the remainder of the world.

STAAR maintains manufacturing and administrative facilities in the United States, Switzerland and Japan. While STAAR has initiated a project to consolidate all of its manufacturing to its Monrovia, California facility, its current global operations are as follows:

United States. STAAR operates its global administrative headquarters and a manufacturing facility in Monrovia, California. The Monrovia manufacturing facility principally makes Collamer and silicone IOLs and injector systems for IOLs and ICLs. STAAR also currently manufactures the raw material for Collamer lenses (both IOLs and ICLs) and the AquaFlow Device (for the treatment of glaucoma) in a facility in Aliso Viejo, California.

Switzerland. STAAR operates an administrative, manufacturing and distribution facility in Nidau, Switzerland under its wholly owned subsidiary, STAAR Surgical AG. The Nidau manufacturing facility makes all of STAAR's Visian ICL products and also manufactures the AquaFlow Device. After consolidating manufacturing in Monrovia, California, STAAR plans to continue to maintain an administrative and distribution facility in Switzerland.

Japan. STAAR operates administrative, manufacturing and distribution facilities in Japan under its wholly owned subsidiary, STAAR Japan Inc. STAAR Japan's administrative facility is located in Shin-Urayasu and its manufacturing and distribution facility is located in Ichikawa City. STAAR currently assembles all of its preloaded IOL injectors at the Ichikawa City facility. After consolidating manufacturing in Monrovia, California, STAAR plans to continue to maintain administrative and distribution facilities in Japan.

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

The Human Eye

The following discussion provides background information on the structure, function and some of the disorders of the human eye to enhance the reader's understanding of our products described in this report. The human eye is a specialized sensory organ capable of receiving visual images and transmitting them to the visual center in the brain. Among the main parts of the eye are the cornea, the iris, the lens, the retina, and the trabecular meshwork. The cornea is the clear window in the front of the eye through which light first passes. The interior surface of the cornea is lined with a single layer of flat, tile-like endothelial cells, whose function is to maintain the transparency of the cornea. The iris is a pigmented muscular curtain located behind the cornea which opens and closes to regulate the amount of light entering the eye through the pupil, an opening at the center of the iris. The natural lens is a clear structure located behind the iris that changes shape to focus light to the retina, located in the back of the eye. The medical term for the natural lens that is present in the eye from birth is “crystalline lens.” The retina is a layer of nerve tissue in the back of the eye consisting of millions of light receptors called rods and cones, which receive the light image and transmit it to the brain via the optic nerve. The posterior chamber of the eye, located behind the iris, is filled with a watery fluid called the aqueous humor, while the portion of the eye behind the lens is filled with a jelly-like material called the vitreous humor. The anterior chamber is the space in the eye behind the cornea and in front of the iris. 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 eye can be affected by common visual disorders, disease or trauma. One of the most prevalent ocular disorders is cataracts. Cataract formation is generally an age-related disorder that involves the hardening and loss of transparency of the natural crystalline lens, impairing visual acuity.

Refractive disorders, which generally are not age-related, include myopia, hyperopia and astigmatism. A normal, well-functioning eye receives images of objects at varying distances from the eye and focuses the images on the retina. Refractive errors occur when the eye's natural optical system does not properly focus an image on the retina. Myopia, also known as nearsightedness, occurs when the eye's lens focuses images in front of the retina. Hyperopia, or farsightedness, occurs when the eye's lens focuses images behind the plane of the retina. Individuals with myopia or hyperopia may also have astigmatism. Astigmatism is blurred vision caused when an irregularly shaped cornea or, in

some cases, a defect in the natural lens, produces a distorted image on the retina. 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.

History of STAAR

STAAR developed, patented, and licensed the first foldable intraocular lens, or IOL, for cataract surgery. Made of pliable material, the foldable IOL permitted surgeons for the first time to replace a cataract patient's natural lens with minimally invasive surgery. The foldable IOL became the standard of care for cataract surgery throughout the world. STAAR introduced its first versions of the lens, made of silicone, in 1991.

In 1996 STAAR began selling the Visian ICL outside the U.S. Made of STAAR's proprietary biocompatible Collamer lens material, the ICL is implanted behind the iris and in front of the patient's natural lens to treat refractive errors such as myopia, hyperopia and astigmatism. 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 ICL received CE Marking in 1997, permitting sale in countries that require the European Union CE Mark, and it received FDA approval for the treatment of myopia in the U.S. in December 2005. The Visian ICL now makes up 51% of our business. We sell it in approximately 60 countries, and it has been implanted in more than 250,000 eyes worldwide.

Other milestones in STAAR's history include the following:

In 1998, STAAR introduced the Toric IOL, the first implantable lens approved for the treatment of preexisting astigmatism. Used in cataract surgery, the Toric IOL was STAAR's first IOL-based solution to a refractive disorder of the eye.

In 2000, STAAR introduced an IOL made of the Collamer material, offering cataract patients and their surgeons the same clarity, refractive qualities and biocompatibility featured by the Visian ICL.

In 2001, STAAR commenced commercial sales of its Visian Toric ICL or TICL, which corrects both astigmatism and myopia, outside the U.S. In 2002, the TICL received CE Marking, allowing commercial sales in countries that require the European Union CE Mark. Today we market the TICL worldwide, except for the U.S.

In late 2003, STAAR Japan introduced the first preloaded IOL lens injector system in international markets. The Preloaded Injector offers surgeons improved convenience and reliability. The Preloaded Injector is not yet available in the U.S.

On December 22, 2005, the FDA approved the Visian ICL for the treatment of myopia, making it the first, and to date only, small incision phakic IOL commercially available in the United States.

Beginning in 2007, STAAR introduced its first aspheric IOLs made of silicone and Collamer.

On December 29, 2007 (fiscal 2008), we acquired the 50% remaining interests in STAAR Japan, making this former joint venture a wholly owned subsidiary of STAAR.

On February 2, 2010, the Japanese Ministry of Health, Labor and Welfare approved the Visian ICL, making it the first phakic IOL approved for sale in Japan.

In September, 2010, STAAR launched the expanded range Visian ICL – Version V4b – in Europe and other territories that recognize the European Union CE Mark. The expanded range allows for the treatment of virtually any myopic or hyperopic refractive error.

In September, 2011, STAAR launched the Visian ICL V4c with CentraFLOW™ technology in Europe and other territories that recognize the CE Mark. CentraFLOW technology uses a proprietary port in the center of the ICL optic. The port has a size determined to optimize the flow of fluid within the eye without affecting the quality of vision, and eliminates the need for the surgeon to perform a YAG peripheral iridotomy procedure days before the ICL implant or a surgical iridotomy at time of implant. By simplifying the procedure and increasing patient comfort,

the V4c makes the superior visual outcomes of the Visian ICL available through a surgical implantation experience closer to LASIK.

·In November, 2011, the Japanese Ministry of Health, Labor and Welfare approved the Toric ICL.

Financial Information about Segments and Geographic Areas

STAAR's principal products are IOLs and ICLs used in ophthalmic surgery. Because STAAR generates 100% of its sales from the ophthalmic surgical product segment, it operates as one operating segment for financial reporting purposes. See Note 19 to the Consolidated Financial Statements for financial information about product lines and operations in geographic areas.

Principal Products

In designing our products we have the following goals:

- To improve patient outcomes,
- To minimize patient risk and discomfort, and
- To simplify ophthalmic procedures or post-operative care for the surgeon and the patient.

Visian ICL (ICLs). ICLs correct refractive disorders such as myopia, hyperopia and astigmatism. The ICL can treat a wide range of refractive errors – the expanded offering of ICLs approved for sale in 2010 in the countries covered by the CE Mark offers a wider range of correction than any other refractive surgical procedure.

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. The surgeon typically implants the ICL using topical anesthesia on an outpatient basis. The patient usually recovers vision within one to 24 hours.

The FDA approved the ICL for myopia for use in the United States on December 22, 2005. Outside the U.S., countries where we may sell the ICL and TICL include the following: the countries that require the European Union CE Mark, China, Canada, Korea, Japan, India, Brazil and Singapore. The ICL for myopia was approved for sale in Japan on February 2, 2010, and the TICL was approved there on November 24, 2011. STAAR submitted its application for U.S. approval of the TICL to the FDA in 2006 and it is currently under review (see “*Regulatory Matters – Regulatory Requirements in the United States – Status of Toric ICL Submission*”).

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

The ICL is available for myopia in the United States in four lengths and 27 powers for each length. Outside the U.S., the ICL is available for myopia and hyperopia and is available in multiple models and lengths in a total of 740 inventoried parts. This requires us to carry a significant amount of inventory to meet the customer demand for rapid delivery. The Toric ICL is available for myopia and hyperopia in the same powers and lengths but carries additional parameters of cylinder and axis. As a result we often make the Toric ICL to order, but we were still able to deliver approximately 69% of our Toric ICLs from stock during 2011.

Sales of ICLs (including TICLs) accounted for approximately 51% of our total sales in fiscal 2011, 44% of our total sales in fiscal 2010, and 41% of our total sales in fiscal 2009.

Minimally Invasive Intraocular Lenses (IOLs). We produce and market a line of foldable IOLs for use in minimally invasive cataract surgical procedures. Because these lenses fold, surgeons can implant them into the eye through an incision less than 3mm in length, and for one model as small as 2.2 mm. Surgeons prefer foldable lenses and small incisions because clinical evidence has overwhelmingly shown that larger incisions can induce corneal astigmatism, extend healing times, and increase the possibility of infection. Once inserted, the IOL unfolds naturally to replace the

cataractous lens.

In most countries government agencies reimburse the cost of cataract surgery and IOLs. Some countries have begun to permit ophthalmic surgeons and surgical centers to collect an additional fee from the cataract patient for products and services that go beyond standard treatment. STAAR's strategic direction is to offer IOLs that fall within the categories that offer an opportunity to increase average selling prices. For example, the U.S. Center for Medicare and Medicaid Services (CMS) reimburses certain "premium" lenses at the standard rate of approximately \$150, but allows the provider to receive an additional payment from the patient for the premium lens and associated services. STAAR's Toric IOL falls in this category.

Currently, our foldable IOLs are manufactured from both our proprietary Collamer material and silicone. STAAR offers both materials in two differently configured styles: the single-piece design where both the optic and haptics are made of the same material and the three-piece design where Polyimide™ loop haptics are attached to the optic. The selection of one style over the other is primarily based on the preference of the ophthalmologist. We also market our silicone and independently sourced acrylic foldable IOLs packaged in a preloaded delivery system in various markets outside the U.S.

STAAR began introducing aspheric IOLs in 2007. Aspheric IOLs use advanced optical designs that produce a clearer image than traditional spherical lenses, especially in low light, which has led to significant market share gains for aspheric designs. STAAR introduced its first aspheric IOLs made of silicone and Collamer in 2007. During 2009, STAAR introduced the nanoFLEX IOL, which has an aspheric optic and can be delivered through a 2.2 mm micro-incision using STAAR's nanoPOINT Injection System.

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

STAAR Japan introduced the first Preloaded Injector in international markets in late 2003. The Preloaded Injector is a silicone or acrylic IOL packaged and shipped in a pre-sterilized, disposable injector ready for use in cataract surgery. We believe the Preloaded Injector offers surgeons improved convenience and reliability. In 2006, STAAR Japan began selling in Japan an acrylic-lens-based Preloaded Injector employing a lens supplied by Nidek Inc., a Japanese ophthalmic company. STAAR now sells the acrylic Preloaded Injector in Europe and other Asian countries as well. Nidek also assembles and sells the acrylic Preloaded Injector under its own brand, using injector parts purchased from STAAR Japan. STAAR Japan's agreement with Nidek provides for the sale of the acrylic Preloaded Injector in additional territories by mutual agreement of the two companies.

Sales of IOLs accounted for approximately 44% of our total sales in fiscal 2011, 50% of our total sales in fiscal 2010 and 52% of our total sales in fiscal 2009.

Other Surgical Products

We also sell other related instruments and devices that we manufacture or that are manufactured by others, but we have deemphasized these products in the past few years due to their relatively lower overall gross profit margins. For example, in 2011 we exited the surgical pack business. Sales of other surgical products accounted for approximately 5% of our total sales in fiscal 2011, 6 % of our total sales in fiscal 2010 and 7% of our total sales in fiscal 2009.

Sources and Availability of Raw Materials

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

Our sources of supply for raw materials can be threatened by shortages and other market forces, by natural disasters, by the supplier's failure to maintain adequate quality or a recall initiated by the supplier. Even when substitute suppliers are available, the need to certify the substitute supplier's regulatory compliance and the quality standards of the replacement material could significantly delay production and materially reduce our sales. We mitigate this risk by maintaining adequate inventory of raw materials when practical and identifying secondary suppliers, but we cannot entirely eliminate the risk. For example, the failure of one of our suppliers could be the result of an unforeseen industry-wide problem, or the failure of our supplier could create an industry-wide shortage affecting secondary

suppliers as well.

In particular, we obtain the proprietary collagen-based raw material used to manufacture our IOLs, ICLs and the AquaFlow Device internally from a sole source, one of our facilities in California. If the supply of these collagen-based raw materials is disrupted we know of no alternative supplier, and therefore, any such disruption could result in our inability to manufacture the products and would have a material adverse effect on STAAR. The loss of our external supply source for silicone could also cause us material harm. In some cases, we mitigate this risk by stockpiling materials, which requires us to devote financial resources to that purpose.

Patents, Trademarks and Licenses

We strive to protect our investment in the research, development, manufacturing and marketing of our products through the use of patents, licenses, trademarks, copyrights, and trade secrets. We own or have rights to a number of patents, licenses, trademarks, copyrights, trade secrets and other intellectual property directly related and important to our business. As of December 30, 2011, we owned approximately 118 United States and foreign patents and had approximately 7 patent applications pending.

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

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

Posterior Chamber Phakic Intraocular Lens to Treat Refractive Errors

The Visian ICL is the only posterior chamber phakic IOL (PIOL) approved for sale in the U.S., and we believe it is the world's largest selling phakic IOL. We believe that our leadership in commercializing this technology results from a number of factors, including proprietary design features and the biocompatibility of the Collamer material. (The proprietary nature of Collamer is discussed in further detail below).

STAAR has several patents covering design features that we believe are essential to the safety and effectiveness of its PIOLs, and that we believe would be necessary or desirable for any competing posterior chamber phakic IOL. These patents expire between 2014 and 2016.

Collamer Lens Material

STAAR believes that the biocompatibility of the Collamer material used for the Visian ICL (and TICL) is a significant factor in the ability to place this lens safely in the posterior chamber of the eye. Compared to lenses placed in the anterior chamber, we believe that placement in the posterior chamber provides superior optical results and superior cosmetic appearance, and poses less risk of damage to the cornea. We believe that the physical and optical properties of Collamer also give it distinct advantages as a material for prosthetic IOLs used in cataract surgery.

Collamer belongs to a family of materials known as *collagen copolymers*. Collagen copolymers are compounds formed by joining molecules of collagen derived from biological sources with synthetic monomer molecules. The patents that underlie the specific formulation and manufacturing methods for Collamer expire between 2014 and 2016.

Lens Delivery Systems

STAAR owns numerous patents covering the technology of foldable lens delivery systems, including injectors, cartridges and preloaded injectors and their specific design features. This group of patents includes relatively recent patents with up to 10 years of life remaining. However, a select group of these patents covering the more fundamental lens delivery technologies will expire between 2012 and 2014.

Trademarks

Worldwide, we sell all of our major products under trademarks we consider to be important to our business. The scope and duration of trademark protection varies widely throughout the world. In some countries, trademark protection continues only as long as the mark is used. Other countries require registration of trademarks and the payment of registration fees. Trademark registrations are generally for fixed but renewable terms.

Confidentiality Agreements

We protect our proprietary technology, in part, through confidentiality and nondisclosure agreements with employees, consultants and other parties. Our confidentiality agreements with employees and consultants generally contain standard provisions requiring those individuals to assign to STAAR, without additional consideration, inventions conceived or reduced to practice by them while employed or retained by STAAR, subject to customary exceptions.

Seasonality

Seasonality does not materially affect our sales.

The first quarter of each fiscal year tends to have the lowest cash flow of the year because of accounting fees related to the annual audit of our financial statements, professional fees for our consultant on internal controls pursuant to the Sarbanes-Oxley Act of 2002, bonus payments, and holiday closures. Holiday closures during December reduce the processing and payment of invoices by STAAR during the last weeks of the fourth quarter, resulting in a significant increase in cash payments by STAAR as it catches up during the first month of the first quarter.

Distribution and Customers

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

We distribute products directly to the physician or facility in the United States, and rely primarily on local distributors in other countries. In Japan, we sell both directly and through a local distributor. Where we distribute products directly, we rely on local sales representatives to help generate sales by promoting and demonstrating our products with physicians. In Japan we generally employ our sales representatives directly. In the U.S., we rely on both directly employed representatives and independent sales representatives to sell our products under the supervision of directly employed sales managers.

A single customer, Woo Jeon Medical Co., Ltd., our Korean distributor, has accounted for more than 10% of our consolidated net revenue in each of the last three fiscal years. Woo Jeon generated the following amounts and percentages of revenue in those years:

Revenue Generated by Woo Jeon

Fiscal Year	Net Revenue (\$, in thousands)	Net Revenue as Percentage of Consolidated Net Revenue
2011	\$8,142	13.0%
2010	\$6,080	11.1%
2009	\$5,366	10.5%

Our U.S.-based internal marketing department develops the strategies used to sell our products in North America and guides our marketing efforts in the Europe/Middle East and Pacific/Asia regions. The marketing department supports selling efforts by developing and providing promotional materials, educational courses, speakers' programs, participation in trade shows and technical presentations.

Backlog

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

The ICL is manufactured to precisely 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, combined with rapidly increasing global demand for the ICL, can result in a backlog in customer orders. Backlog is not currently at a significant level in relation to our total annual sales. However, unexpectedly large orders for ICLs could increase our backlog. STAAR believes it has sufficient capacity to ramp up production levels to meet demand and that any backlogs will be temporary. However, delays in filling orders can result in lost sales if alternative refractive treatments are available to the patient. Because Toric ICLs treat an even greater variety of refractive errors and at times must be custom made for the patient, customers are accustomed to a special order procedure and do not expect immediate delivery of Toric ICLs from inventory.

Government Contracts

No material portion of our business is subject to renegotiation of profits or termination of contracts or subcontracts at the election of the U.S. Government.

Competition

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

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

We believe our primary competition in selling the Visian ICL to patients seeking surgery to correct refractive conditions lies not in similar products, but in the much better known and widely available laser surgical procedures. Novartis (formerly Alcon); Abbott Medical Optics (“Abbott”), previously known as Advanced Medical Optics (“AMO”); and Bausch & Lomb (“B&L”) all market excimer lasers for corneal refractive surgery and promote their sales worldwide. Approval of custom laser ablation, along with the addition of wavefront technology, has increased awareness of corneal refractive surgery by patients and practitioners. We believe that a majority of patients treated with the Visian ICL continue to learn about the product after initially seeking laser surgery. Improving consumer awareness of the Visian ICL is therefore a primary objective of STAAR.

Phakic implants that compete with the Visian ICL are also available in the marketplace. The three principal types of phakic IOLs (PIOLs) are posterior chamber designs like the Visian ICL, iris clip anterior chamber PIOLs like the Artisan® and Artiflex® lenses made by Ophtec (Artisan® is distributed in the U.S. by AMO under the Verisyse® brand), and angle-supported anterior chamber PIOLs like the Cachet™ made by Alcon and sold outside the U.S. We believe the Visian ICL has compelling clinical advantages over the other lenses, which are reflected in our 75% market share of the global phakic IOL market. Over the past 24 months we have introduced line extensions that have extended the treatment range of the ICL, improved its safety profile and enhanced its ease of use. These enhancements position the technology as an even more compelling alternative to laser vision correction. The Visian ICL is the only foldable, minimally invasive PIOL approved for sale in the U.S.

As with the refractive market, the global cataract market is highly concentrated, with the top three competitors (Novartis, Abbott and B&L) combined accounting for around 85% of total market revenue, according to a 2011 report by Market Scope, LLC, a publisher of ophthalmic industry analysis. These three competitors are well established, have extensive product portfolios and have significantly greater resources than does STAAR, making it difficult to compete with them on a broad market basis. To optimize the effectiveness of our efforts in the cataract market we compete solely with differentiated products in the foldable IOL/injection system segment of the market. Our lenses are differentiated based on at least one of the following: lens material, design of the optics or advantages of the injection system.

Our differentiated IOL portfolio includes lenses made from our proprietary Collamer lens material. This material has the highest water content of any material in the market, giving it excellent biocompatible properties and providing our lenses with unrivaled optical quality. The single piece Collamer lens with aspheric optics is sold under the nanoFLEX brand and can be inserted via a 2.2mm incision using the nanoPOINT® injector system. In late 2009, a group of surgeons referred to by STAAR as the Collamer Accommodating Study Team (CAST) reported that the nanoFLEX IOL exhibited some near and intermediate vision improving properties. It has also been reported that the nanoFLEX lens may be especially appropriate when used for monovision. *Monovision* is a treatment strategy for presbyopia that corrects one eye (the dominant eye) for distance vision, and corrects the other eye to provide near vision. It is reported that after surgery most patients undergo a neural adaptation that lets them fuse the near vision from one eye with the distance vision from the other. A survey conducted by Market Scope in the first quarter of 2010 found that, based on responses from 484 surgeons, an average of 12.9% of cataract procedures performed in the US market employed a monovision strategy. We received CE mark approval for nanoFLEX in early 2011 and for the toric version of the lens

designed to treat astigmatism – nanoFLEX Toric during the fourth quarter of 2011.

Silicone IOLs account for around 67% of our total IOL sales. Outside of the US these are differentiated using the STAAR propriety preloaded injector system, the KS3-Ai brand. US approval for the preloaded silicone IOL is expected in 2012. Within the US market we offer a toric silicone IOL under the brand STAARToric®. This lens is positioned as a premium channel IOL for which a surgeon can charge an additional fee to the patient beyond standard Medicare reimbursement. We are in the process of rationalizing our range of standard monofocal silicone IOLs.

Outside of the US we offer the KS-X preloaded acrylic lens in Japan and in markets covered by CE approval. We differentiate product from other acrylic IOLs in the marketplace with the KS-X preloaded delivery system which enables the surgeon to efficiently deliver the lens into the eye through a 2.8 millimeter incision.

Regulatory Matters

Nearly all countries where we sell our products have regulations requiring advance approval or certification of medical devices. Various federal, state, local and foreign laws also apply to our operations, including, among other things, working conditions, laboratory and manufacturing practices, and the use and disposal of hazardous or potentially hazardous substances.

The requirements for approval or clearance to market medical products vary widely by country. The requirements range from minimal requirements to requirements comparable to those established by the U.S. Food and Drug Administration (“FDA”). For example, many countries in South America and the Middle East have minimal regulatory requirements, while many others, such as Japan, have requirements of similarly stringency to those of the FDA. Obtaining approval to distribute medical products is costly and time-consuming in virtually all of the major markets where we sell medical devices. We cannot assure that any new medical devices we develop will be approved in a timely or cost-effective manner or approved at all. The regulatory requirements in our most important current markets, the U.S., Europe and Japan, are discussed below.

Regulatory Requirements in the United States.

Under the federal Food, Drug & Cosmetic Act, as amended (the “Act”), the FDA has the authority to adopt, and has adopted, regulations that do the following:

- set standards for medical devices,

- require proof of safety and effectiveness prior to marketing devices that the FDA believes require pre-market approval,

- require approval prior to clinical evaluation of human use,

- permit detailed inspections of device manufacturing facilities,

- establish “good manufacturing practices” that must be followed in device manufacture,

- require reporting of serious product defects, associated adverse events, and certain recalls or field actions to the FDA, and

- prohibit the export of devices that do not comply with the Act unless they comply with specified requirements, including but not limited to requirements that exported devices comply with applicable foreign regulations, do not conflict with foreign laws, and that the export not be contrary to public health in the U.S. or the importing country.

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

The FDA establishes procedures for compliance based upon regulations that designate devices as Class I (general controls, such as establishment registration and device listing with FDA, labeling and record-keeping requirements), Class II (performance standards in addition to general controls) or Class III (pre-market approval (“PMA”) required before commercial marketing). Class III devices are the most extensively regulated because the FDA has determined they are life-supporting, are of substantial importance in preventing impairment of health, or present a potential unreasonable risk of illness or injury. The effect of assigning a device to Class III is to require each manufacturer to submit to the FDA a PMA that includes information on the safety and effectiveness of the device. The FDA reviews

device applications and notifications through its Office of Device Evaluation, or “ODE.”

510(k) Clearance. A medical device that is substantially equivalent to a directly related medical device previously in commerce may be eligible for the FDA’s pre-market notification “510(k) review” 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, but merely means that the medical device is substantially equivalent to a previously cleared commercial medical device. The review period and FDA determination as to substantial equivalence generally is made within 90 days of submission of a 510(k) application, unless additional information or clarification or clinical studies are requested or required by the FDA. As a practical matter, the review process and FDA determination may take longer than 90 days.

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 significantly affects safety or effectiveness. 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 premarket approval is obtained. If the FDA requires us to seek 510(k) clearance or premarket approval for any modifications to a previously cleared product, we may be required to cease marketing or recall the modified device until we obtain this clearance or approval. Also, in these circumstances, we may be subject to significant regulatory fines or penalties.

In July 2011 the Institute of Medicine published a study requested by the FDA on whether legislative, regulatory or administrative changes are needed to the FDA's 510(k) process. The Institute found "that the current 510(k) process is flawed based on its legislative foundation. Rather than continuing to modify the 35-year-old 510(k) process . . . the FDA's finite resources would be better invested in developing an integrated premarket and post market regulatory framework that provides a reasonable assurance of safety and effectiveness throughout the device life cycle." The Institute recommended additional data gathering to develop such a new framework. The FDA also announced an internal working group to evaluate and improve the consistency of FDA decision making in the clearance process, and recently released an internal report in which FDA officials questioned the 510(k) process in general. Various committees of the U.S. Congress also have indicated that they may consider investigating the FDA's 510(k) process. If any of these actions result in a limitation or elimination of the 510(k) approval path STAAR may find it much more costly and time consuming to develop and introduce new products in the U.S.

Premarket Approval. When 510(k) clearance is not available, the more rigorous PMA process requires us to demonstrate independently that the new medical device is safe and effective. As an initial step the process of developing the product must be stringently managed and documented – along with any later changes in design – in a "design history file" that will be submitted with the PMA. The next step is pre-clinical testing, which includes chemical analysis, toxicity testing and other bench testing, and animal trials. The results of this early testing are submitted to the FDA along with a detailed research plan. Only after approval of this submission can a non-approved device receive an "investigational device exemption" or IDE, which permits the device to be used to treat human subjects in a supervised study.

Clinical trials on human subjects are expensive and time consuming, often taking years from design to completion. The trial, once approved, is subject to extensive oversight. In addition to FDA oversight through the ODE and the FDA's Division of Bioresearch Monitoring ("BIMO"), the company sponsoring the research must designate a private Independent Review Board ("IRB") to approve and monitor the research and assure that it is ethical, scientifically sound and regulated. The company sponsoring the research must adopt and observe stringent procedures for overseeing research, collecting and analyzing data, and will be subject to BIMO audits to verify compliance.

If clinical research supports the safety and efficacy of the device, the sponsor prepares and submits the PMA, which consists of several volumes and includes not only research data and analysis, but also design history files. 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.

Following its review, the FDA will authorize commercial release if it determines there is reasonable assurance that the medical device is safe and effective. The FDA makes this decision based on a determination that the device's benefit outweighs the risk to the population for which treatment with the device is intended.

If a manufacturer plans to modify an approved PMA device in a manner that affects safety or effectiveness, 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 a change that *enhances* safety prior to the FDA’s review of the PMA Supplement. The FDA designates some PMA Supplements as “panel track” supplements, which means that the agency believes review by an advisory panel may be warranted. Designation as a panel-track supplement does not necessarily mean that panel review will actually occur.

Our IOLs, ICLs, and AquaFlow Devices are Class III devices, and our lens injector systems are Class I devices. We have received PMA approval for our IOLs, the ICL for the treatment of myopia, and the AquaFlow Device. We have received 510(k) clearance for our lens injector systems.

Oversight of compliance with quality, medical device reporting and other regulations. Both before and after we release a product commercially, we have ongoing responsibilities under FDA regulations. The FDA Office of Compliance reviews design and manufacturing practices, labeling and record keeping, and manufacturers’ required reports of adverse experiences and other information to identify potential problems with marketed medical devices. We are also subject to periodic inspection by the FDA for compliance with the FDA’s quality system regulations and requirements, such as restrictions on advertising and promotion. The Good Manufacturing Practice (“GMP”) regulations govern the methods used in, and the facilities and controls used for, the design, manufacture, packaging and servicing of all finished medical devices intended for human use. 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 risks of substantial harm to the 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 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.

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

FDA Reviews of STAAR's Quality Systems. The FDA's most recent general quality inspections of STAAR's facilities were regularly scheduled inspections of the Nidau, Switzerland facility between June 2 and June 5, 2009, of the Monrovia, California facility on January 25, 2012, and of the Aliso Viejo, California facility on November 22, 2010. The inspection of the Nidau, Switzerland facility that concluded on June 5, 2009 resulted in the inspector issuing two observations of nonconformity on Form FDA-483. STAAR agreed with the observations and at the conclusion of the inspection both of the observations were annotated as corrected and one was additionally annotated as verified. The inspections of the Monrovia, California and Aliso Viejo, California facilities resulted in no observations of noncompliance. Based in part on these inspections, STAAR believes that it is substantially in compliance with the FDA's Quality System Regulations and Medical Device Reporting regulations.

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

Status of TICL Submission. STAAR submitted a Pre-Market Approval Application (PMA) supplement for the TICL to the FDA on April 28, 2006, which the agency has designated as a panel-track supplement. In August 2007, following negative inspectional observations and a Warning Letter from FDA's Division of Bioresearch Monitoring ("BIMO"), the FDA Office of Device Evaluation placed an integrity hold on STAAR's TICL application. Over a two-year period STAAR took a number of corrective actions to address BIMO's concerns and to remove the integrity hold, including engaging an independent third party to conduct a 100% audit of patient records in the TICL clinical study, along with an audit of clinical systems to ensure accuracy and completeness of data before resubmitting the application. On July 21, 2009, the FDA notified STAAR that as a result of STAAR's corrective actions the FDA had removed the integrity hold on our application for approval of the TICL, and would resume its consideration of the application. During August and September 2009, the agency and STAAR resolved a number of questions related to the TICL supplement in an interactive process. On February 3, 2010, STAAR received a letter of deficiency from the FDA outlining additional questions. On August 2, 2010 we responded to the FDA's deficiency letter. Since that response, STAAR has been in dialogue with the agency, working interactively to resolve a series of follow-up questions. On April 22, 2011, STAAR responded to the most recent questions from the agency, which concerned the basis for an increase in the number of reported patient follow-up visits following the independent third party audit of the clinical data, and has responded to additional follow-up questions after that date. On November 29, 2011 STAAR received a letter of deficiency from FDA further questioning the clinical data, specifically the inclusion of patient data that was obtained outside the study windows, requesting additional information on the lens design and a validation report for the Toric ICL power calculation software. STAAR has sent a preliminary response seeking clarification of the FDA's position on the study cohort. STAAR cannot predict when, or if, the FDA may grant approval of the Visian Toric ICL.

Regulatory Requirements outside the United States.

CE Marking. The member countries of the European Union require that all medical products sold within their borders carry a *Conformité Européenne* Mark (“CE Mark”). The CE Mark on a medical device indicates that it has been found to comply with European Directives and associated guidelines concerning the design and manufacture of medical devices, including clinical trials, labeling, quality control, technical specifications, adverse event reporting, and biological, chemical and clinical safety. We have obtained the CE Mark for all of our principal products including ICL and TICL products, IOLs, injector systems and our AquaFlow Device.

A CE Marked device may be sold throughout the 27 countries in Europe. Other countries, such as Switzerland, have voluntarily adopted laws and regulations that mirror those of the European Union with respect to medical devices, and a number of countries outside of Europe permit importation of devices bearing the CE Mark. 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 approve medical devices and to monitor quality systems and adverse event reporting. The independent Notified Bodies perform, on a privatized basis, functions similar to the FDA in the U.S. and the PMDA in Japan. Our facilities in the U.S., Japan and Switzerland are all subject to regular inspection by a designated Notified Body.

Medical Device Regulation in Japan. The Japanese Ministry of Health, Labor, and Welfare (MHLW) regulates the sale of medical devices under Japan's Pharmaceutical Affairs Law (PAL). The Pharmaceutical 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* (pre-market device approval) or *ninsho* (certification). Manufacturers and resellers (referred to as Marketing Authorization Holders or MAHs) must also satisfy certain requirements before the MHLW grants a business license, or *kyoka*. Requirements for manufacturers and MAHs include compliance with Japanese regulations covering GQP (good quality control practice) and GVP (good vigilance practice), which largely include conformity to the ISO 13485 standard and are similar to good manufacturing practice and post-market surveillance requirements in the U.S., 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 Visian 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 postmarket data gathered within a certain period - normally four years - after approval. The specific postmarket reexamination requirement for a medical device is announced at the time of approval.

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

Research and Development

We focus on furthering technological advancements in the ophthalmic products industry through the development of innovative premium ophthalmic products and materials and related surgical techniques. We maintain an active internal research and development programs, which also includes clinical activities and regulatory affairs and is comprised of 26 employees. In order to achieve our business objectives, we will continue our investment in research and development.

During the last few years STAAR has regularly introduced new products from its pipeline of research and development projects. For example, during 2011, STAAR introduced the Visian ICL V4c with CentraFLOW™ technology in Europe and other territories that recognize the CE Mark, and launched the Toric ICL in Japan. During the first half of 2012 STAAR will introduce the nanoFLEX™ Toric Collamer IOL in countries that accept the CE Mark. During 2010 it introduced the nanoPOINT™ 2.0 microincision injector for the ICL and launched an expanded range of Visian ICL products in countries that accept the CE Mark. During 2009 STAAR introduced the nanoFLEX™ Aspheric Collamer IOL, which can be delivered through the nanoPOINT injector, and the advanced Epiphany™ injector system for the Affinity Collamer IOL. Outside the U.S. in 2009 STAAR introduced the KS-X Preloaded Hydrophobic Acrylic Injector System in Europe and the KS-Ni Preloaded Silicone IOL Injector System in Japan.

During 2012, our goal is to continue our focus on research and development in the following areas:

- Enhancements to the ICL that may simplify the procedure and further improve its efficacy
- Development of preloaded injector systems for Collamer ICLs and IOLs
- Introduction of a hydrophobic acrylic single-piece preloaded injector system outside the U.S.
- Development of accommodating or presbyopic IOLs
- Introduction of the silicone preloaded injector system in the U.S.

Research and development expenses were approximately \$5.9 million, \$5.7 million and \$5.9 million for our 2011, 2010 and 2009 fiscal years, respectively. STAAR expects to invest approximately 9-10% of sales for research and development in 2012.

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.

Significant Subsidiaries

As of March 1, 2012, STAAR's principal subsidiaries were STAAR Surgical AG in Switzerland and STAAR Japan Inc., both of which STAAR wholly owns. The activities of each are described above.

Employees

As of March 1, 2012, we employed approximately 297 persons.

Code of Ethics

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

Additional Information

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

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

Glossary

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

accommodation – the eye’s ability to adjust its focus at all distances between near and far. This ability tends to decline with age.

accommodating IOL – a type of IOL designed to restore some degree of variable near-and-far focus after cataract surgery.

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.

anterior chamber – the space in the eye between the cornea and the iris.

aqueous humor – a clear, watery fluid that fills the anterior chamber. Some important tissues of the eye, including the cornea and the crystalline lens, do not have blood vessels and receive their nourishment from the flow of the aqueous humor.

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.

astigmatism is a refractive disorder in which partially blurred vision results from an irregularly shaped cornea or, in some cases, a defect in the natural lens, produces a distorted image on the retina. The astigmatic eye is sometimes said to be slightly football-shaped rather than being a perfect sphere.

blended vision– a name used by some surgeons to refer to a modified monovision strategy for cataract patients. Using IOLs like nanoFLEX that provide a certain degree of intermediate vision, the surgeon corrects the two eyes for near and far vision with a difference between eyes that is less than conventional monovision, averaging 1.3 diopters. Surgeons using this method have reported that patients adapt to blended vision more readily than to conventional monovision, and report good binocular vision at all distances.

cataract – a common age-related eye disorder that involves the hardening and loss of transparency of the natural crystalline lens, impairing visual acuity.

CMS – an acronym for the Centers for Medicare and Medicaid Services, the federal agency that establishes and administers rules for the U.S. Medicare and Medicaid reimbursement systems.

collagen copolymer - collagen copolymers are 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.

Collamer® - the brand name for STAAR's proprietary collagen copolymer lens material. Collamer is composed of a poly-HEMA-based copolymer, collagen and a UV-absorbing chromophore. Collamer lenses have high water content, are biocompatible and are designed to mimic the optical properties and flexibility of the natural lens in the human eye.

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.

decentration – decentration of an IOL is a displacement of an IOL after implantation in the eye such that the IOL's central axis is not perfectly aligned with the visual axis of the eye. STAAR developed its proprietary aspheric design to perform well even if decentered.

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.

glaucoma – a progressive and degenerative condition, usually associated with elevated fluid pressure in the eye, in which the optic nerve may be damaged, resulting in irreversible loss of vision. Glaucoma is a leading cause of blindness worldwide.

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. A person with hyperopia cannot see close objects without glasses or contact lenses. Because presbyopia often results in the need for reading glasses, it is sometimes confused with farsightedness.

HICL – an acronym for a Visian ICL product used to treat hyperopia (farsightedness).

ICL – an acronym for “implantable Collamer lens,” the Visian ICL is a folding lens implanted in the eye to correct refractive errors like myopia that have traditionally been corrected with eyeglasses or contact lenses. The ICL is within a product category referred to as *phakic IOLS* or *phakic implants* because they work with the patient’s natural lens, or *phakos*, rather than replacing it.

intraocular – within the eye.

IOL- an acronym for “intraocular lens,” this is the general term for any type of lens designed to be surgically implanted in the eye. When we use the term “IOL” without modification, we mean a prosthetic lens used to replace the natural crystalline lens after cataract surgery.

iris – the muscular curtain located behind the cornea, which opens and closes to regulate the amount of light entering the eye through the pupil, which is an opening at the center of the iris. The iris carries the blue or brown pigment that gives the eye its color.

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.

iridectomy – a small hole surgically created in the iris as an alternative to the iridotomy described below. Some surgeons prefer to use iridectomies because they can be performed in the same surgical session as Visian ICL implantation, resulting in less discomfort and inconvenience for the patient.

iridotomy – a small hole created in the iris, usually made with a YAG laser. Prior to implantation of some Visian ICL models a YAG *peripheral* iridotomy is made in an obtrusive area at the periphery of the iris to ensure continued fluid flow in the eye after implantation. The Visian V4c model has a central port for fluid flow, which eliminates the need for an iridotomy or iridectomy.

AquaPORT™ - a proprietary port in the center of the ICL optic of a size determined to optimize the flow of fluid within the eye without affecting quality of vision.

laser eye surgery – a generic term for LASIK and PRK.

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

monovision – a strategy for treating presbyopia where one eye – usually the dominant one – is corrected for distance vision and the other is corrected for near vision. This treatment method, which has been used with contact lenses and LASIK and with IOLs in cataract patients, depends on the patient’s neural visual system adapting to fuse the differing information into a continuous visual field from near to far. Because of the significant disparity between the correction of the two eyes – usually 1.5D to 2.0D – depth perception and contrast sensitivity are somewhat compromised by monovision and some patients cannot tolerate it at all.

multifocal IOL – a type of IOL that creates zones in the visual field for distance, far and near vision, similar to the near and far zones in bifocal glasses.

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

nanoFLEX – a single-piece Collamer aspheric IOL that can be implanted through a 2.2 mm incision with the complementary nanoPOINT injector system.

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

optometrist - a doctor who diagnoses disorders of the eye and prescribes eyeglasses and contact lenses for refractive disorders, but does not perform surgery.

ophthalmic – of or related to the eye.

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

phakic IOL or phakic implant – an artificial lens that is implanted to work along with the patient’s natural lens is called a phakic IOL or phakic implant, from the Greek word for lens, *phakos*. This is the product class to which the Visian line of products belongs. IOLs that treat cataracts are sometimes called *aphakic IOLs* because they are implanted in patients whose natural lenses have been removed.

phacoemulsification is a small-incision procedure used to remove a cataract patient’s cloudy lens before implantation of an IOL. Phacoemulsification uses ultrasound to break up the tissue of the crystalline lens, and then uses suction to draw the tissue out through the small incision.

PMMA IOLs are IOLs made of polymethylmethacrylate, an inflexible material largely replaced by flexible materials such as acrylic and silicone.

posterior chamber is the space in eye behind the iris and in front of the natural crystalline lens.

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

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

presbyopic IOLs are IOLs that are designed to restore some degree of near and far visual acuity after cataract surgery.

PRK – an acronym for *photorefractive keratectomy*, a surgical operation that reshapes the surface of the cornea to correct nearsightedness, farsightedness and astigmatism. PRK involves the use of an *excimer laser* to ablate, or burn, small amounts of tissue from the cornea. PRK differs from LASIK, which employs a flap to gain access to the corneal bed, then uses the excimer laser to shape the corneal bed rather than the surface of the cornea.

refractive disorders are visual disorders that affect the ability of the eye’s optical system to create a sharply focused image. Refractive disorders include myopia (nearsightedness), hyperopia (farsightedness), astigmatism and presbyopia. These are the visual disorders that have traditionally been treated with eyeglasses and contact lenses, and more recently with refractive surgery. Glaucoma, cataracts and macular degeneration are examples of visual impairment that are *not* refractive disorders.

refractive market – as used in this report “refractive market” means the overall market volume for refractive surgical procedures of all kinds, including LASIK, PRK, the Visian 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.

refractive surgery – operative procedures intended to correct or reduce refractive disorders. In addition to the implantation of the Visian ICL, common refractive surgeries include LASIK and PRK.

retina - a layer of nerve tissue at 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.

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

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

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

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

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

TICL – an acronym for “Toric implantable Collamer lens,” a variant of the ICL that corrects astigmatism as well as myopia or hyperopia.

Visian – STAAR’s brand name for its family of posterior chamber phakic intraocular lenses, including the Visian ICL, Visian TICL and Visian HICL.

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

Item 1A. Risk Factors

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

Risks Related to Our Business

We compete with much larger companies.

Our competitors, including Alcon, Abbott Medical Optics and Bausch & Lomb have much greater financial resources than we do and some of them have large international markets for a full suite of ophthalmic products. Their greater resources for research, development and marketing, and their greater capacity to offer comprehensive products and equipment to providers, make it difficult for us to compete. We have lost significant market share to some of our competitors.

FDA compliance issues have delayed approvals and we expect to devote significant resources to maintaining compliance in the future.

The Office of Compliance of the FDA's Center for Devices and Radiological Health regularly inspects STAAR's facilities to determine whether we are in compliance with the FDA Quality System Regulations relating to such things as manufacturing practices, validation, testing, quality control, product labeling and complaint handling, and in compliance with FDA Medical Device Reporting regulations and other FDA regulations. The FDA also regularly inspects for compliance with regulations governing clinical investigations.

Based on the results of regularly scheduled inspections of the Nidau, Switzerland facility between June 2 and June 5, 2009 and of the Monrovia, California facility on January 25, 2012, STAAR believes that it is substantially in compliance with the FDA's Quality System Regulations and Medical Device Reporting regulations. However, past quality system deficiencies observed at STAAR have led to FDA Warning Letters and delays in product approvals until we resolved agency concerns. Past deficiencies in clinical study procedures, practices and documentation related to the TICL led the FDA to place an integrity hold on the TICL application in August 2007, which was lifted in July 2009.

STAAR's ability to continue its U.S. business depends on the continuous improvement of its quality systems and constant vigilance in its compliance with FDA regulations. Accordingly, for the foreseeable future STAAR's management expects to continue to devote significant resources and attention to those efforts. STAAR cannot ensure that its efforts will be successful. Any failure to demonstrate substantial compliance with FDA regulations can result in enforcement actions that terminate, suspend or severely restrict our ability to continue manufacturing and selling medical devices. Please see the related risks discussed under the headings "*We are subject to extensive government regulation, which increases our costs and could prevent us from selling our products*" and "*We are subject to federal and state regulatory investigations.*"

FDA approval of the Toric ICL, which could have a significant U.S. market, has been considerably delayed.

An important part of STAAR's Visian ICL product portfolio is the Toric ICL, or TICL, a variant of the ICL that corrects both astigmatism and myopia in a single lens and that is currently marketed outside the U.S. STAAR believes the TICL has a significant potential market in the U.S. and could accelerate growth of the overall refractive product line. STAAR submitted a supplemental PMA for the TICL in April 2006, which remains subject to FDA review and a number of pending questions under discussion with the agency. Without the Toric ICL the Visian product line is not

likely to reach its full market potential in the U.S., and STAAR cannot predict when or if the FDA will approve it.

The global nature of our business may result in fluctuations and declines in our sales and profits.

Our products are sold in approximately 60 countries. Sales from international operations make up a significant portion of our total sales. For the fiscal year ended December 30, 2011, sales from international operations were 78% of our total sales. The results of operations and the financial position of certain of our foreign operations are reported in the relevant local currencies and then translated into U.S. dollars at the applicable exchange rates for inclusion in our consolidated financial statements, exposing us to translation risk. In addition, we are exposed to transaction risk because some of our sales and expenses are incurred in a different currency from the local currency. Our most significant currency exposures are to the Japanese yen, the euro, and the Swiss franc. The exchange rates between these and other local currencies and the U.S. dollar may fluctuate substantially. We have not attempted to offset our exposure to these risks by investing in derivatives or engaging in other hedging transactions.

Economic, social and political conditions, laws, practices and local customs vary widely among the countries in which we sell our products. Our operations outside of the U.S. face a number of risks and potential costs, enjoy less stringent protection of intellectual property and face economic, political and social uncertainty in some countries, especially in emerging markets. Our continued success as a global company depends, in part, on our ability to develop and implement policies and strategies that are effective in anticipating and managing these and other risks in the countries where we do business. These and other risks may have a material adverse effect on our operations in any particular country and on our business as a whole. We price some of our products in U.S. dollars, and as a result changes in exchange rates can make our products more expensive in some offshore markets and reduce our sales. Inflation in emerging markets also makes our products more expensive there and increases the credit risks to which we are exposed.

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. We could be particularly hurt if any key employee or employees went to work for competitors. 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 have a history of losses that could continue in the future.

During 2011 STAAR achieved net income from continuing operations after reporting losses for more than ten years. STAAR has just crossed the threshold of profitability, and sustained profitability remains vulnerable to the

competitive nature of our industry and the other risks to our business detailed below. We have an accumulated deficit of \$130.7 million as of December 30, 2011.

We rely on depend on independent distributors in international markets.

Except for North America and Japan, STAAR sells its products through independent distributors who are 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. Because we do not have local staff in most of the areas covered by independent distributors, it may be difficult for us to detect failures in our distributors' performance or compliance. Actions by independent distributors that are beyond our control could result in flat or declining sales in that territory, harm to the reputation of our company or its products, or legal liability.

The success of our international operations depends on our successfully managing our foreign subsidiaries.

We conduct most of our international business through wholly owned subsidiaries. Managing distant subsidiaries and fully integrating them into STAAR's business is challenging. While STAAR seeks to integrate its foreign subsidiaries fully into its operations, direct supervision of every aspect of their operations is impossible, and as a result STAAR relies on its local managers and staff. Cultural factors, language differences and the local legal climate can result in misunderstandings among internationally dispersed personnel, and increase the risk of failing to meet U.S. and foreign legal requirements, including with respect to the Sarbanes-Oxley Act of 2002 and the U.S. Foreign Corrupt Practices Act. These risks increased after we completed the acquisition of STAAR Japan Inc. and remain significant. The risk that unauthorized conduct may go undetected will always be greater in foreign subsidiaries.

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, or the FCPA. Any failure to comply with these laws, even if inadvertent, could result in significant penalties or otherwise harm our reputation and business. Our reliance on foreign subsidiaries and independent distributors demands a high degree of vigilance in maintaining our policy against participation in corrupt activity. In many of our markets outside the U.S., doctors and hospital administrators may be deemed government officials. Other U.S. companies in the medical device and pharmaceutical field have faced criminal penalties under the FCPA for allowing their agents to deviate from appropriate practices in doing business with such individuals.

Unfavorable economic conditions hurt sales of our refractive products.

Refractive surgery is an elective procedure generally not covered by health insurance. Patients must pay for the procedure, frequently through installment financing arrangements. 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. Laser refractive surgery experienced a significant decrease in demand globally with the recession that began in mid-2008, and has not fully recovered. While Visian ICL sales have continued to grow globally, STAAR believes that negative economic conditions have slowed growth, especially in the U.S. Economic stagnation, lack of consumer confidence or new recessions in any of our key markets could further slow Visian ICL sales growth or, if severe, cause declines in sales. Because the Visian ICL is STAAR's fastest growing and highest gross margin product, restricted growth or a decline in its sales could materially harm STAAR's business.

Negative publicity concerning complications of laser eye surgery could reduce the demand for our refractive products as well.

Negative publicity about laser eye surgery has appeared in the U.S. and some other refractive surgery markets. On April 25, 2008, the FDA Ophthalmic Devices Panel held a public meeting to discuss reports of medical complications and customer satisfaction following refractive surgery. The resulting publicity broadened public awareness of the potential complications of refractive surgery and potential patient dissatisfaction, in particular as a result of LASIK and other corneal laser-based procedures. In May 2009 the FDA issued a cautionary letter to surgeons regarding promotion and advertising of lasers used in refractive surgery. In October 2009 the FDA, in collaboration with the National Eye Institute and the U.S. Department of Defense, began a major study on the quality of life for patients after LASIK surgery, which is to be concluded in 2012. The results of this study could amplify concerns about complications of laser refractive surgery. While these concerns could encourage patients and doctors to select the Visian ICL as an alternative, they could also decrease patient interest in all refractive surgery, including Visian ICL. Depending on the nature and severity of future negative publicity about refractive surgery, the growth of ICL sales in the U.S. could be limited or sales could decline as a result. Because nearly all candidates for refractive surgery can achieve acceptable vision through the use of spectacles or contact lenses, for most patients the decision to have refractive surgery is a lifestyle choice that depends on high confidence in achieving a satisfactory outcome.

We may not realize the expected benefits of our manufacturing consolidation project and tax strategies.

Beginning in 2011 STAAR has invested significant resources in a manufacturing consolidation project and a tax strategy initiative, and it expects to invest several million dollars to complete the projects. The goal of these projects is to increase profit margins by improving manufacturing efficiency, simplifying administrative and regulatory functions, and reducing tax liabilities. We cannot assure that we will achieve the expected benefits of these initiatives. Among other things, costs could exceed current estimates, product manufacturing transfers can be affected by delays

or cause supply interruptions, changes in tax laws could reduce or eliminate expected benefits of some of our tax strategies, and future profit margins can be affected by a variety of factors unrelated to our level of manufacturing efficiency.

Our manufacturing consolidation plan exposes us to risk.

Transferring the manufacturing of medical devices is more expensive, time-consuming and risky than similar transfers in less regulated industries. In our major markets, regulatory approval to sell our products is generally limited to the current manufacturing site, and changing the site will require 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 made at a new site are equivalent to those made at the currently approved site. Even minor changes in equipment, supplies or processes require validation. While STAAR has placed a priority on maintaining the continuity and quality of its product supply, unanticipated delays or difficulties in the transfer process could interrupt our supply of products. Any sustained interruption in supply could cause us to lose market share and harm our business.

We may experience backlog in ICL orders due to rapid increases in demand.

The challenge of maintaining inventory across the large number of ICL models, combined with rapidly increasing global demand for the ICL, has from time to time resulted in a backlog in customer orders. While the dollar amount of backlog orders is not currently significant in relation to our total annual sales, unexpectedly large orders for ICLs could increase our backlog to levels that are financially significant. In addition, delays in filling orders can result in lost sales if alternative refractive treatments are available to the patient. If we are unable to ramp up production to meet growing demand we may not achieve our growth targets.

We could experience losses due to product liability claims.

We have been subject to product liability claims in the past and may experience such claims in the future. Product liability claims against us may exceed the coverage limits of our insurance policies or cause us to record a loss in excess of our deductible. A product liability claim that exceeds our insurance coverage could materially harm our business, financial condition and results of operations. Even if a product liability loss is covered by an insurance policy, 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 amount of claims could have a material adverse effect on our business, financial condition, and results of operations.

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

not have a material adverse effect on our business.

We may have limited ability to fully use our recorded tax loss carryforwards.

We have accumulated approximately \$121.1 million of U.S. federal tax net operating loss carryforwards as of December 30, 2011, which can be used to offset taxable income in future quarters if our U.S. operations become profitable. If unused, these tax loss carryforwards will begin to expire between 2020 and 2031. Although we currently generate profits on a consolidated basis, those profits are generated outside the U.S. and are subject to relatively high income taxes that we cannot offset with U.S. loss carryforwards. As part of our global consolidation strategy we plan to locate our profit generating activities in the U.S., but unexpected changes in tax laws or delays and complications in our consolidation efforts could prevent us from realizing the benefits of this tax strategy. Moreover, under the current tax laws, if we were to experience a significant change in ownership, Internal Revenue Code Section 382 may restrict the future utilization of these tax loss carryforwards even if our U.S. operations generate significant profits.

We are subject to international tax laws that could affect our financial results.

STAAR conducts international operations through its subsidiaries. Tax laws affecting international operations are highly complex and subject to change. STAAR's payment of income tax in the different countries where it operates depends in part on internal settlement prices and administrative charges among STAAR and its subsidiaries. These arrangements require judgments by STAAR and are subject to risk that tax authorities will disagree with those judgments and impose additional taxes, penalties or interest on STAAR. In addition, transactions that STAAR has arranged in light of current tax rules could have unforeseeable negative consequences if tax rules change.

We have only limited working capital and limited access to financing.

We began generating cash from operations in 2009 after six consecutive years when our cash requirements exceeded the level of cash generated by operations. We may not be able to sustain positive cash flow, and unexpected cash needs could exceed the amount of cash we generate. While we believe our capital resources and funds generated by operations are sufficient to operate our business and satisfy our obligations, if unexpected events increase our expenses or harm the performance of our business we may need to seek additional financing. We may also be presented with opportunities to expand our business that require additional financing. Should we need additional working capital, our ability to raise financing through sales of equity securities depends on general market conditions and the demand for STAAR's common stock. We may be unable to raise adequate capital through sales of equity securities, and if our stock has a low market price at the time of such sales our existing stockholders could experience substantial dilution. Because of our history of losses STAAR may also have difficulty obtaining debt financing on acceptable terms or renewing existing debt facilities. An inability to secure additional financing if it is needed in the future could require us to forego opportunities for expansion, reduce existing operations, or even jeopardize our ability to continue operations.

If we suffer loss to our facilities due to catastrophe, our operations could be seriously harmed.

We depend on the continuing operation of our manufacturing facilities in California, Japan and Switzerland, which have little redundancy or overlap among their activities. Our facilities could suffer catastrophic loss due to fire, flood, earthquake, terrorism or other natural or man-made disasters. Our California and Japanese facilities are in areas where earthquakes could cause catastrophic loss. If any of these facilities were to experience a catastrophic loss, it could disrupt our operations, delay production, shipments and revenue and result in large expenses to repair or replace the facility. We plan to consolidate all of our manufacturing to our Monrovia, California facility, which will increase our exposure to a disaster that occurs in that area. Our insurance for property damage and business interruption may not be sufficient to cover any particular loss. We do not carry insurance or reserve funds for interruptions or potential losses arising from earthquakes or terrorism.

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. Both plans are underfunded and may require significant cash payments. During 2011, we contributed \$275,000 to our Swiss Plan, and although we did not contribute to our Japan Plan, we made benefit payment of \$38,000.

Beginning October 1, 2009, as part of the Amendment of the Japan Plan discussed in Note 13 to the consolidated financial statements included in this report, STAAR Japan has maintained and administered the Japan Plan, including paying the pension benefits as they are due solely from its continuing operations. STAAR Japan is not required to make any contributions to the Japan Plan in order to meet future pension benefit obligations, and does not expect to do so. As a result, STAAR Japan has no plan assets now and does not expect to have any in the future.

STAAR determines its pension benefit obligations and funding status using many assumptions, such as inflation, investment rates, mortality, turnover and interest rates, as applicable, any of which could prove to be different than projected. 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 in the aggregate are underfunded by approximately \$2.8 million (\$1.1 million for the Japan Plan and \$1.7 million for the Swiss Plan) as of December 30, 2011.

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

Our activities involve hazardous materials and emissions and may subject us to environmental liability.

Our manufacturing, research and development activities involve the use of hazardous materials. 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 completely eliminate the risk of accidental contamination or injury from these materials. Remedial environmental actions could require us to incur substantial unexpected costs, which would materially and adversely affect our results of operations. If we were involved in an environmental accident or found to be in substantial non-compliance with applicable environmental laws, we could be held liable for damages or penalized with fines.

Most of our products have single-site manufacturing approvals, exposing us to risks of business interruption.

We manufacture all of our products at our facilities in California, Switzerland, and Japan. Most of our products are approved for manufacturing only at one of these sites. Before we can use a second manufacturing site for an implantable device we must obtain the approval of regulatory authorities. Because this process is expensive we have generally not sought approvals needed to manufacture at an additional site. If a natural disaster, fire, or other serious business interruption struck one of our manufacturing facilities, it could take a significant amount of time to validate a second site and replace lost product. We could lose customers to competitors, thereby reducing sales, profitability and market share. While our insurance covers lost revenue resulting from business interruption for a number of causes, if we have no product supplies for an extended period we could suffer an unrecoverable loss of market share. We do not have insurance coverage for revenue lost in a business interruption following an earthquake. Once completed, our manufacturing consolidation plan could increase the risk of harm to our business from a natural disaster in California.

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

We depend on information technology networks and systems, including the Internet, to process, transmit and store electronic information. In particular, our information technology infrastructure handles electronic communications among our locations around the world and between our personnel and our subsidiaries, customers, and suppliers. Security breaches of this infrastructure can create system disruptions, shutdowns or unauthorized disclosure of confidential information. If we are unable to prevent such security breaches, our operations could be disrupted or we may suffer financial damage or loss because of lost or misappropriated information.

Changes in accounting standards could affect our financial results.

The accounting rules applicable to public companies like STAAR are subject to frequent revision. Future changes in accounting standards could require us to change the way we calculate income, expense or balance sheet data, which could significantly change our reported results of operations or financial condition.

Risks Related to the Ophthalmic Products Industry

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

Medical devices must be manufactured to the highest standards and tolerances, and often incorporate newly developed technology. From time to time defects or technical flaws in medical devices may not come to light until after the products are sold or consigned. In those circumstances, like others in our industry, we have voluntarily recalled our products. Similar recalls could take place again. We may also be subject to recalls initiated by manufacturers of products we distribute. Courts or regulators can also impose mandatory recalls on us, even if we believe our products are safe and effective. STAAR believes that in recent years it has been less affected by recalls than most of its U.S. competitors, but 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. 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, and the damage to our reputation, could cause professionals to discontinue using our products.

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

Constant development of new technologies and techniques, frequent new product introductions and strong price competition characterize the ophthalmic industry. The first company to introduce a new product or technique to market usually gains a significant competitive advantage. Our future growth depends, in part, on our ability to develop products to treat diseases and disorders of the eye that are more effective, safer, or incorporate emerging technologies better than our competitors' products. 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 fail to make sufficient investments in research and development or if we focus on technologies that do not lead to better products, our current and planned products could be surpassed by more effective or advanced products. In addition, we must manufacture these products economically and market them successfully by persuading a sufficient number of eye-care professionals to use them.

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

We spent about 9.3% of our sales on research and development during the fiscal year ended December 30, 2011, and we expect to spend similar amounts for this purpose in future periods. Development of new implantable technology, from discovery through testing and registration to initial product launch, is expensive and typically takes from three to seven years. Because of the complexities and uncertainties of ophthalmic research and development, products we are currently developing may not complete the development process or obtain the regulatory approvals required for us to market the products successfully. Any of the products currently under development may fail to become commercially successful.

Changes in reimbursement for our products by third-party payors could reduce sales of our products or make them less profitable.

Many of our products, in particular IOLs and products related to the treatment of glaucoma, are used in procedures that are typically covered by health insurance, HMO plans, Medicare, Medicaid, or other governmental sponsored programs both in and outside the U.S. Third party payors in both government and the private sector continue to seek to manage costs by restricting the types of procedures they reimburse to those viewed as most cost-effective and by capping or reducing reimbursement rates. Whether they limit reimbursement prices for our products or limit the surgical fees for a procedure that uses our products, these policies can reduce the sales volume of our reimbursed products, their selling prices or both. Future cost cutting initiatives could result in unexpected reductions in the reimbursement rates for IOLs and related products. In some countries government insurers have sought to control costs by limiting the total number of procedures they will reimburse. The U.S. Congress is currently considering legislative proposals that would significantly change the system of public and private health care reimbursement, and will likely consider such changes again in the future. We are not able to predict whether new legislation or changes in regulations will take effect at the state or federal level, but if enacted these changes could significantly and adversely affect our business.

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

STAAR is regulated by regional, national, state and local agencies. In the U.S. our regulators include the Food and Drug Administration, the Department of Justice, the Federal Trade Commission, the Office of the Inspector General of the U.S. Department of Health and Human Services and other regulatory bodies, as well as governmental authorities in those foreign countries in which we manufacture or distribute products. The Federal Food, Drug, and Cosmetic Act, the Public Health Service Act and other federal and state statutes and regulations govern the research, development, manufacturing and commercial activities relating to medical devices, including their pre-clinical and clinical testing, approval, production, labeling, sale, distribution, import, export, post-market surveillance, advertising, dissemination of information and promotion.

We are subject to similar regulatory regimes in other key regions of Europe and Asia, in particular Japan. Regulations worldwide are becoming more stringent. We have described in detail the regulations governing approval of medical devices and their manufacturing in the “*Business – Regulatory Matters*” section of this Report. We are also subject to government regulation over the prices we charge and any rebates we may offer to customers. 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 approval. Obtaining approval can be a long and expensive process, and approval is never certain. In addition, our operations are subject to periodic inspection by the FDA and international regulators. An unfavorable outcome in an FDA inspection may result in the FDA ordering changes in our business practices or taking other enforcement action, which could be costly and severely harm our business.

Our new products could take a significantly longer time than we expect to gain regulatory approval and may never gain approval. If a regulatory authority delays approval of a potentially significant product, the potential sales of the product and its value to us can be substantially reduced. Even if the FDA or another regulatory agency approves a product, the approval may limit the indicated uses of the product, or may otherwise limit our ability to promote, sell and distribute the product, or may require post-marketing studies. If we cannot obtain timely regulatory approval of our new products, or if the approval is too narrow, we will not be able to market these products, which would eliminate or reduce our potential sales and earnings.

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

Failure to comply with the requirements of the FDA or other regulators can result in civil and criminal fines, the recall of products, the total or partial suspension of manufacture or distribution, seizure of products, injunctions, whistleblower 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.

From time to time STAAR is subject to formal and informal inquiries by regulatory agencies, which could lead to investigations or enforcement actions. Even when an inquiry results in no evidence of wrongdoing, is inconclusive or is otherwise not pursued, the agency generally is not required to notify STAAR of its findings and may not inform STAAR that the inquiry has been terminated.

STAAR maintains a hotline for employees to report any violation of laws, regulations or company policies anonymously, which is intended to permit STAAR to identify and remedy improper conduct. Nevertheless, present or former employees may elect to bring complaints to regulators and enforcement agencies. The relevant agency will generally be obligated to investigate such complaints to assess their validity and obtain evidence of any violation that may have occurred. In response to reports that its policies or applicable laws or regulations have been violated, STAAR may find it necessary to conduct its own intense investigations, which may be extensive. Even without a finding of misconduct, negative publicity about investigations or allegations of misconduct could harm our reputation with professionals and the market for our common stock. Responding to investigations or conducting internal investigations can be costly, time-consuming and disruptive to our business.

Strikes, slow-downs or other job actions by doctors can reduce sales of cataract-related products.

In many countries where STAAR sells its products, doctors, including ophthalmologists, are employees of the government, government-sponsored enterprises or large health maintenance organizations. In recent years employed doctors who object to salary limitations, working rules, reimbursement policies or other conditions have sought redress through strikes, slow-downs and other job actions. These actions often result in the deferral of non-essential procedures, such as cataract surgeries, which affects sales of our products. Depending on the importance of the affected region to STAAR's business, the length of the action and its pervasiveness, job actions by doctors can materially reduce our sales and earnings.

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

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

· cease selling or using any of our products that incorporate the challenged intellectual property, which would adversely affect our sales;

· negotiate a license from the holder of the intellectual property right alleged to have been infringed, which license may not be available on reasonable terms, if at all; or

· redesign our products to avoid infringing the intellectual property rights of a third party, which may be costly and time-consuming or impossible to accomplish.

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

Most of our products are covered by patents that, if valid, give us a degree of market exclusivity during the term of the patent. We have also earned revenue in the past by licensing some of our patented technology to other ophthalmic companies. Generally, the legal life of a patent in the U.S. is 20 years from application. Patents covering our products will expire from this year through the next 20 years. Upon patent expiration, our competitors may introduce products using the same technology. Key patents covering the Collamer formulation and essential design features of the Visian ICL and TICL will expire between 2014 and 2016. As a result of this possible increase in competition, we 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 prior to the expiration of patents for our existing products, our sales and profits with respect to those products could decline significantly. We may not be able to develop and successfully launch more advanced replacement products before these and other patents expire.

Risks Related to Ownership of Our Common Stock

Our charter documents could delay or prevent an acquisition or sale of our company.

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

· stockholders have limited ability to remove directors;

· stockholders cannot act by written consent;

· stockholders cannot call a special meeting of stockholders;

· the above limitations on stockholder action can be changed only by a 66-2/3% supermajority vote of stockholders; and

· stockholders must give advance notice to nominate directors.

Anti-takeover provisions of Delaware law could delay or prevent an acquisition of our company.

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

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

Our Board of Directors could issue additional shares of common or preferred stock to raise additional capital or for other corporate purposes without stockholder approval. In addition, the Board of Directors could designate and sell a class of preferred stock with preferential rights over the common stock with respect to dividends or other distributions. Also, STAAR has filed a universal “shelf registration statement” with the Securities and Exchange Commission. The shelf registration statement covers the future public offering and sale of up to \$75 million in equity or debt securities or any combination of such securities. While STAAR currently has no plans to issue any securities under the shelf registration, sales of common or preferred stock under the shelf registration or in other transactions could dilute the interest of existing stockholders and reduce the market price of our common stock. Even in the absence of such sales, the perception among investors that additional sales of equity securities may take place could reduce the market price of our common stock.

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

Our stock price has fluctuated widely. It ranged from \$4.48 to \$11.50 per share during the year ended December 30, 2011 and was \$11.00 on March 2, 2012. Our stock price could continue to experience significant fluctuations in response to factors such as market perceptions, quarterly variations in operating results, operating results that vary from the expectations of securities analysts and investors, changes in financial estimates, changes in market valuations of competitors, announcements by us or our competitors of a material nature, additions or departures of key personnel, future sales of Common Stock and stock volume fluctuations. Also, general political and economic conditions such as recession or interest rate fluctuations may adversely affect the market price of our stock.

Item 1B. Unresolved Staff Comments

None

Item 2. Properties

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

Item 3. Legal Proceedings

From time to time the Company is subject to various claims and legal proceedings arising out of the normal course of our business. These claims and legal proceedings relate to contractual rights and obligations, employment matters, and claims of product liability. STAAR maintains insurance coverage for product liability claims but may not be insured against other potentially material claims. While the Company does not believe that any of the claims known is likely to have a material adverse effect on its financial condition or results of operations, new claims or unexpected results of existing claims could lead to significant financial harm.

Item 4. Mine Safety Disclosure

None

PART II**Item 5. Market for Registrant’s Common Equity, Related Stockholder Matters, and Issuer Purchases of Equity Securities***Market Information*

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

Period	High	Low
Year ended December 30, 2011		
Fourth Quarter	\$11.50	\$7.20
Third Quarter	8.50	4.48
Second Quarter	5.92	4.56
First Quarter	6.41	5.05
Year ended December 31, 2010		
Fourth Quarter	\$6.28	\$4.89
Third Quarter	6.74	4.20
Second Quarter	5.98	3.56
First Quarter	3.97	3.00

*Holder*s

As of March 2, 2012, there were approximately 462 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 29, 2006 through December 30, 2011 of the total performance of the following:

- STAAR Surgical Company;
- The Nasdaq Stock Market;

a peer group we have selected consisting of 12 companies within our industry or closely related industries: Anika Therapeutics (ANIK); Cutera Inc. (CUTR); Cynosure Inc. (CYNO); Integra LifeSciences Holdings Corp. (IART); Iridex Corp. (IRIX); LCA Vision Inc. (LCAV); Merit Medical Systems, Inc. (MMSI); Palomar Medical Technologies Inc. (PMTI); Solta Medical Inc. (SLTM); Synergetics USA Inc. (SURG); Syneron Medical Ltd. (ELOS); and Volcano Corporation (VOLC); and

publicly traded companies that have been classified within Standard Industrial Classification (SIC) Codes 3841-3851 (Surgical, Medical, Dental instruments and Supplies and Ophthalmic Goods).

In 2011, STAAR’s Board of Directors selected a peer group of public companies to be used as a benchmark to measure the Company’s performance and to provide comparisons for compensation decisions. For the peer index in its last Annual Report on Form 10-K, STAAR had used public companies classified within SIC Codes 3841-3851. STAAR believes that because the new peer group more closely reflects STAAR’s industry, size and business model it provides a better frame of reference to measure STAAR’s performance, and that it provides more useful information to both management and investors. During this year of transition, the graph continues to show a performance line for the previously used SIC-code-based group along with the performance line for the newly selected peer index

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 29, 2006 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.

Prepared by Zacks Investment Research, Inc. Used with Permission. All rights reserved.

Total Returns Index for:	12/2006	12/2007	1/2009	1/2010	12/2010	12/2011
STAAR Surgical Company	100.00	37.09	34.38	44.22	87.02	149.64
The Nasdaq Stock Market (US and Foreign Companies)	100.00	111.47	68.60	96.33	113.94	112.98
Peer Group	100.00	70.49	52.28	58.43	73.19	63.25
NASDAQ SIC 3841-3851 (Surgical, Medical, Dental Instruments and Supplies and Ophthalmic Goods)	100.00	110.43	75.75	98.13	100.77	97.45

Notes:

- A. The lines represent monthly index levels derived from compounded daily returns that include all dividends.
- B. The indexes are reweighted daily, using the market capitalization on 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 \$100.0 on December 29, 2006.

Item 6. Selected Financial Data

The following table sets forth selected consolidated financial data with respect to the five most recent fiscal years ended December 30, 2011, December 31, 2010, January 1, 2010, January 2, 2009, and December 28, 2007. The selected consolidated statement of operations data set forth below for each of the three most recent fiscal years, and the selected consolidated balance sheet data set forth below at December 30, 2011 and December 31, 2010, are derived from our consolidated financial statements, which have been audited by BDO USA, LLP, our independent registered public accounting firm, as indicated in their report included in this Annual Report. The selected consolidated statement of operations data set forth below for each of the two fiscal years in the periods ended January 2, 2009 and December 28, 2007 and the consolidated balance sheet data set forth below at January 1, 2010, January 2, 2009, and December 28, 2007 are derived from audited consolidated financial statements of the Company not included in this Annual Report. We have adjusted all prior periods presented to account for Domilens GmbH divestiture on March 2, 2010 and present Domilens as a discontinued operation. The selected consolidated financial data should be read in conjunction with the consolidated financial statements of the Company, and the Notes thereto, included in this Annual Report, and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” in Item 7.

	Fiscal Year Ended				
	December 30, 2011	December 31, 2010	January 1, 2010	January 2, 2009	December 28, 2007
	(In thousands except per share data)				
Statement of Operations					
Net sales	\$62,765	\$54,958	\$51,060	\$49,770	\$35,632
Cost of sales	20,396	19,882	19,737	20,688	16,176
Gross profit	42,369	35,076	31,323	29,082	19,456
General and administrative	14,932	14,778	15,009	15,730	12,309
Marketing and selling	17,726	17,176	15,300	18,472	15,868
Research and development	5,868	5,724	5,893	7,938	6,711
Other general and administrative expenses	1,060	—	—	9,773	—
Operating income (loss)	2,783	(2,602)	(4,879)	(22,831)	(15,432)
Total other expense, net	(79)	(1,079)	(869)	(1,044)	(917)
Income (loss) before income taxes	2,704	(3,681)	(5,748)	(23,875)	(16,349)
Income tax provision	1,356	432	1,154	975	883
Income (loss) from continuing operations	1,348	(4,113)	(6,902)	(24,850)	(17,232)
Income from discontinued operations, net of income taxes	—	4,166	702	1,655	1,233
Net income (loss)	\$1,348	\$53	\$(6,200)	\$(23,195)	\$(15,999)
Income (loss) per share from continuing operations	\$0.04	\$(0.12)	\$(0.21)	\$(0.84)	\$(0.61)
– basic					
Income (loss) per share from continuing operations	\$0.04	\$(0.12)	\$(0.21)	\$(0.84)	\$(0.61)
– diluted					

Edgar Filing: STAAR SURGICAL CO - Form 10-K

Income per share from discontinued operations, basic and diluted	\$—	\$ 0.12	\$ 0.02	\$ 0.05	\$ 0.04
Net income (loss) per share – basic	\$0.04	\$ (0.00)	\$ (0.19)	\$ (0.79)	\$ (0.57)
Net income (loss) per share – diluted	\$0.04	\$ (0.00)	\$ (0.19)	\$ (0.79)	\$ (0.57)
Weighted average shares outstanding-basic	35,434	34,825	32,498	29,474	28,121
Weighted average shares outstanding –diluted	36,878	34,825	32,498	29,474	28,121
Balance Sheet Data					
Working capital	\$24,638	\$ 16,539	\$ 13,466	\$10,807	\$ 21,006
Total assets	49,006	40,585	58,681	52,582	54,179
Long-term notes payable, net of discount	—	—	—	* 4,414	4,166
Other long-term liabilities	5,532	4,711	3,887	3,910	2,500
Stockholders' equity	29,458	22,427	21,070	16,027	36,225

* included in current liabilities

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

The matters addressed in Management's Discussion and Analysis of Financial Condition and Results of Operations 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," "project," "intend," "believe," "will," "target," "forecast" and similar expressions in connection with any discussion of future operating or financial performance. In particular, these include statements relating to future actions, prospective products or product approvals, future performance or results of current and anticipated products, sales efforts, expenses, interest rates, foreign exchange rates, the outcome of contingencies, such as legal proceedings, and financial results.

Although the Company believes that the expectations reflected in these forward-looking statements are reasonable, such statements are inherently subject to risks and the Company can give no assurance that its 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 the control of the Company. These factors include, without limitation, those described in this Annual Report in "Item 1A — Risk Factors." The Company undertakes 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

Strategy

STAAR's strategy is to be valued as a leading global provider of innovative intraocular lens system technologies. STAAR employs a commercialization strategy that focuses on achieving sustainable profitable growth.

Performance Against 2011 Key Operational Metrics

Two principal strategic goals guided STAAR's key operational metrics in 2011: to achieve and maintain profitability and to lay the groundwork for further growth. In pursuit of these goals, STAAR aligned its business initiatives during 2011 along four key operational metrics that it used to gauge its success during the year. Based on performance in excess of targets during the second quarter, STAAR increased the targets for three of the four metrics, and in final form they are as follows:

- Increase total revenue by double digits.
- Grow Visian ICL and TICL sales by 30%.
- Continuously increase gross profit margin each quarter to achieve a level of 66.5% for the full year.
- Achieve profitability in all four quarters of 2011.

As detailed below, STAAR satisfied all four of the metrics during 2011.

Increase total revenue by double digits. By placing less emphasis on less profitable non-core products, STAAR has both increased its revenue and increased the portion of its revenue derived from higher value core products. STAAR set a target of double digit growth in total revenue during 2011. STAAR achieved 13.9% growth in the fourth quarter of 2011 and 14.2% growth for the year.

Grow Visian ICL and TICL sales by 30%. STAAR achieved 37% growth rate in Visian ICL and TICL sales in the fourth quarter of 2011 and a 32% growth rate for the year. We have been pursuing the goal of increased ICL and TICL sales by identifying the top ten markets and concentrating our sales and marketing efforts on increasing our market share in those regions. Growth rates in the top ten markets on which we currently focus were 45% for the fourth quarter and 35% for the year. STAAR launched its new Visian V4c with CentraFLOW™ technology in the countries covered by the CE Mark late in the fourth quarter of 2011. U.S. ICL sales have continued a trend of relatively slow growth seen over the last two years, growing at 2% for the year. Early in 2011 we had set an original goal to increase Visian ICL and TICL sales by 25%; we increased the goal after exceeding the target level in the second quarter. Because Visian products are used in elective surgery, the rate of sales growth depends on continued improvement in global economic conditions. We discuss recent trends in Visian sales in greater detail below under the heading *Visian ICL and TICL sales*.

Continuously expand gross profit margin each quarter to achieve a level of 66.5% for the full year. STAAR's gross profit margin was 69.8% in the fourth quarter and 67.5% for the year. The biggest factor in the improving margins has been the change in our product mix. Visian products yield a significantly higher profit margin than IOLs. And among IOLs, STAAR has increased average selling prices by emphasizing sales of its higher value IOLs, such as nanoFLEX and our Toric IOL. Preloaded IOL sales in some territories, especially Japan, have historically yielded good profit margins and their sales increased 5% during 2011. Since 2009 STAAR has de-emphasized lower margin sales of non-IOL, non-ICL products. Based on performance in the first half of 2011, STAAR raised its gross profit margin target to 66.5% for the full year from an initial target of 66% at year end. STAAR believes it can continue to improve its profit margins through further emphasis on high value products, through cost reductions from its manufacturing consolidation plan, and potentially through economies of scale if unit volumes of higher value products increase.

Achieve profitability in all four quarters of 2011. STAAR achieved net earnings of \$1.3 million in 2011, or \$0.04 per share. In the fourth quarter STAAR achieved net earnings of \$0.1 million, or \$0.00 per share. STAAR's achievement of net earnings of \$0.3 million in the first quarter of 2011 marked the first quarter since 1999 during which the company reported net income from continuing operations. Based on first and second quarter results, STAAR increased this metric from an original target of profitability in three of four quarters, and targeted profits during each quarter of the year. We caution that STAAR has just crossed the threshold of profitability, and sustained profitability remains vulnerable to the competitive nature of our industry and to the risk factors described in our Annual Report on Form 10-K.

Other Highlights

Global Visian ICL and TICL Sales

STAAR continues to focus its Visian marketing and sales efforts in the top ten refractive markets, based on the success of this strategy from 2009 through 2011. These markets include the U.S., Japan, Korea, China, India, Spain, Middle East, Germany, U.K., and Latin America.

Since 2009, STAAR has experienced a breakthrough in market penetration in Korea, where it believes implants of Visian products have reached approximately 13.4% of the total volume of refractive surgery procedures. Revenues from sales of Visian ICL products in Korea increased 54% in the fourth quarter and 34% for the year. Because of the rapid growth of Visian ICL sales and market share in Korea, STAAR is using Korea as a model of best practices for marketing that may serve to significantly increase market share in other key territories. Other territories where Visian products experienced significant growth in 2011 over prior year were China, Japan, Germany, the Middle East and India.

In September 2011, STAAR launched the V4c model of the Visian ICL with CentraFLOW technology in countries that recognize the CE Mark. The CentraFLOW technology uses a proprietary port in the center of the ICL optic of a size determined to optimize the flow of fluid within the eye, and eliminates the need for the surgeon to perform a YAG peripheral iridotomy procedure days before the ICL implant or a surgical iridotomy at time of implant. By simplifying the procedure and increasing patient comfort, the V4c makes the superior visual outcomes of the Visian ICL available through a surgical implantation experience closer to LASIK, which should attract new surgeons and patients to the product. Uptake of the new product exceeded STAAR's expectations in the fourth quarter of 2011, as approximately 25% of the Visian ICL and TICL sales volume in Europe transitioned to V4c. STAAR expects its customers' enthusiasm for the simplified V4c procedure to drive increased Visian ICL sales in 2012.

The launch of V4c follows the September 2010 introduction of the V4b model, which offers an expanded range of correction, in territories that recognize the CE Mark. The expanded range includes ICLs with lower levels of myopia correction in quarter-diopter increments, Toric hyperopic ICLs to treat astigmatism and far-sightedness, and Toric ICLs in the low to zero range of myopia to treat patients primarily affected by astigmatism. These product line extensions more than double the number of patients who could benefit from Visian products in Europe and other territories that accept the CE Mark. In 2011, approximately 7% of the V4b sales in the markets where it has been available were in the new expanded treatment range.

STAAR believes that, where available, the V4c and V4b models have significantly improved the competitiveness of the Visian product line and have moved STAAR closer to its goal of positioning the ICL and TICL throughout the world as primary choices for refractive surgery. Visian products now address all degrees of refractive error that can be treated with laser eye surgery, as well as moderate and severe errors beyond the effective range of laser eye surgery.

In some key markets of the Asia Pacific region STAAR has not yet introduced the V4b. STAAR is seeking approval of the V4c and plans to move directly to that model as quickly as regulatory timelines allow.

STAAR received approval to sell the TICL in Japan on November 24, 2011. Current approvals in Japan cover the V4 models of ICL and TICL. STAAR will seek approval for the V4c as well. STAAR is seeking approval of the TICL in U.S., the only remaining significant Visian market where approval has not been issued.

STAAR's ability to maintain or accelerate the rate of growth in Visian ICL sales will partly depend on continued improvement in worldwide economic conditions and progress with regulatory agencies. ICL surgery is a relatively expensive elective procedure and is seldom reimbursed by insurers or government agencies. STAAR believes that the global recession reduced overall demand for refractive surgery particularly in the U.S., and it has been reported that consumer spending and consumer confidence has not returned to pre-recession levels.

In May 2011 STAAR received approval to market the Visian model V4 ICL in Brazil. This approval helped to drive STAAR's decision to target the Latin American market for Visian ICL growth, and we have added sales and marketing resources in the region to capitalize on the new opportunity. In addition, STAAR is working to expand regulatory approvals in the market.

We consider Visian ICL sales growth in the U.S. market important because of the size of the U.S. refractive surgery market and the perceived worldwide leadership of the U.S. in adopting innovative medical technologies. The Visian ICL was approved by the FDA for treatment of myopia on December 22, 2005.

U.S. sales of ICLs increased by 15.8% in the fourth quarter and 1.5% for the year, compared to prior year. Sales in the private sector continued to increase, up by 24.2% in the quarter and were up 12.8% for the year. Sales to the military declined by 31.3% in the quarter bringing the year to date decline to 35.8%. Military sales accounted for 14.7% of total US ICL sales during 2011, compared to 23.3% in 2010. STAAR believes the increase in private sector sales resulted from its efforts to drive greater adoption and increased usage of the lower diopter range among its existing customer base. If the economy continues to improve, and overall refractive procedures volume increases, STAAR could see further growth in private sector ICL sales in the U.S.

Beginning the fourth quarter of 2010 STAAR has been testing direct-to-consumer advertising initiatives online and has used conventional direct-to-consumer media to test a campaign in selected markets. This activity seeks to increase potential refractive patient visits and to encourage patients to inquire specifically about the Visian ICL by distinguishing it from other refractive treatments. The current materials for the campaign are a series of humorous videos contrasting the Visian ICL with LASIK, eyeglasses and contact lenses. The videos highlight certain benefits of the ICL over other treatments, including clarity of vision, absence of surgically induced dry eye, removability and ultraviolet protection. STAAR is assessing the data obtained to date to determine whether, and in what form, to launch a broader direct-to-consumer campaign

Additionally, STAAR has begun efforts to increase the visibility of the Visian ICL technology on social network sites. Contestants developed videos in which they tried to convince voters why they needed a free Visian ICL procedure. STAAR worked with nine ophthalmic practices across the U.S., and five winners were determined based on consumer voting on the network. In most cases the winners' Visian ICL procedures attracted favorable local media attention. During the October 2011 American Academy of Ophthalmology meeting, STAAR offered online marketing consulting for key practices to support their viral efforts around the Visian ICL technology. STAAR has decided to expand its social networking department in 2012 in order to more effectively drive consumer testimonials and respond to consumer questions.

Global IOL Sales.

STAAR pioneered the development of folding lenses for use in cataract surgery, and IOLs continue to represent approximately 44% of STAAR's business. Sales of IOLs during the three months and year ended December 30, 2011 were \$6.8 million and \$27.5 million, compared to \$7.1 million and \$27.5 million for the same periods in the prior year.

In September 2011, STAAR launched its nanoFLEX Collamer Single Piece IOL which can be injected through a 2.2 mm incision with the nanoPOINT™ Injector System, in the territories that recognize the CE Mark. STAAR received CE Mark approval to market its nanoFLEX toric IOL in November 2011, and expects to begin marketing the lens during the first half of 2012. nanoFLEX is STAAR's largest selling IOL product in U.S. markets and STAAR believes the lens can receive broad commercial acceptance outside the U.S. STAAR hopes that the biocompatibility and outstanding optical properties of Collamer, with which surgeons have become acquainted through the ICL, will build interest in the nanoFLEX IOL worldwide. Availability of the toric version of the lens, which corrects pre-existing astigmatism at the time of cataract surgery, is expected to increase interest in the nanoFLEX technology. STAAR's Collamer Accommodating Study Team (CAST) has reported promising assessments regarding initial intermediate and near vision results with the nanoFLEX lens. These properties of nanoFLEX may also spur interest in the lens in new markets, especially among surgeons seeking an IOL for monovision treatment.

STAAR has marketed its silicone toric IOL since 1998 and believes that the addition of the nanoFLEX toric will make the product line more competitive with acrylic toric IOLs now in the market. Among other things, the nanoFLEX toric features an aspheric optic, and we believe the bioadhesive nature of the Collamer material will provide excellent rotational stability, a key characteristic for toric lenses.

Among STAAR's initiatives to grow its IOL business are the following:

- we plan to seek further approvals for the nanoFLEX and nanoFLEX Toric in an effort to build a global product franchise for Collamer IOLs;
- a new version of the hydrophobic acrylic Preloaded Injector, featuring the popular single-piece IOL format, received CE Mark approval in May 2011, and STAAR plans to introduce it into international markets in 2012;
- we plan to introduce a preloaded injector for the nanoFLEX and nanoFLEX toric;
- we have recently seen renewed interest in our silicone Toric IOL among U.S. surgeons and are ramping up marketing efforts for the lens; and
- we are seeking approval to introduce the silicone Preloaded Injector in the U.S. market to enhance our U.S. IOL offering and help STAAR maintain or increase its market share in the hospital-based segment;
- we are researching accommodating and/or multifocal designs that exploit the unique optical properties of the Collamer material.

STAAR cautions that the successful development and introduction of new products is subject to risks and uncertainties, including the risk of unexpected delays and, in some cases, approval of regulatory authorities.

Manufacturing Consolidation Project and Tax Strategy. During 2011 STAAR devoted significant resources to two initiatives: a project to consolidate global manufacturing, and development of a strategy to optimize our global organization for tax purposes. The goal of both of these strategies is to continue our improvement in gross profit margin by reducing costs and to position the company for future growth.

STAAR currently manufactures its products in four facilities worldwide. It has developed a plan to methodically consolidate its manufacturing in a single site at its Monrovia, California location by the end of 2013, which is expected subsequently to yield significant savings in cost of goods and to lower our global administrative and regulatory costs.

In addition, as STAAR's profitability grows, its liability for income taxes in various jurisdictions has also increased. STAAR has developed a strategy to minimize its future tax liabilities as its business grows. Among other things, STAAR seeks to utilize the approximately \$121.1 million in net operating losses that it has accumulated in the U.S.

In connection with its Centers of Excellence project in 2009 and 2010, STAAR successfully transferred manufacturing of some of its products; STAAR believes this experience will be helpful in undertaking the more ambitious transfers involved in the manufacturing consolidation project.

STAAR expects these initiatives to cost approximately \$6 million over a three-year period, of which it spent approximately \$1.1 million during 2011. Expenditures to date have largely consisted of professional fees to advisors and consultants and accruals for asset retirement obligations. Additionally, we expect to spend approximately \$2.4 million in capital expenditures to consolidate our manufacturing.

However, we cannot assure that we will achieve the expected benefits of these initiatives. Among other things, costs could exceed current estimates, product manufacturing transfers can result in delays or supply interruptions, changes in tax laws could reduce or eliminate expected benefits of some of our tax strategies, and future profit margins can be affected by a variety of factors unrelated to our level of manufacturing efficiency.

Effect of Earthquake on Japan Operations. On March 11, 2011, a 9.0 magnitude earthquake struck northeastern Japan, followed by a tsunami that devastated the region's coastal communities. STAAR Japan's staff and their immediate families suffered no serious injuries. STAAR's manufacturing facilities in Ichikawa City, Chiba Prefecture, suffered only minor damage and resumed operations on Wednesday, March 16, 2011. Despite the disaster, STAAR Japan's revenues and its domestic IOL and ICL business have continued to grow; revenues in 2011 were 7% higher than prior year. Nevertheless, widespread disruptions in the Japanese economy and infrastructure may have slowed the rate of growth in STAAR Japan's recently launched ICL business, and that effect may continue until recovery is complete.

Backlog. The ICL is manufactured to precisely 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, combined with rapidly increasing global demand for the ICL, can result in a backlog in customer orders. While the dollar amount of backlog orders is not currently significant in relation to our total annual sales, unexpectedly large orders for ICLs could increase our backlog. STAAR believes it has sufficient capacity to ramp up production levels to meet demand and that any backlogs will be temporary. However, delays in filling orders can result in lost sales if alternative refractive treatments are available to the patient. Because Toric ICLs treat an even greater variety of refractive errors and at times must be custom made for the patient, they are accustomed to a special order procedure and do not expect immediate delivery of Toric ICLs from inventory.

Status of U.S. TICL Submission. STAAR submitted a Pre-Market Approval Application (PMA) supplement for the TICL to the FDA on April 28, 2006, which the agency has designated as a panel-track supplement. In August 2007, following negative inspectional observations and a Warning Letter from FDA's Division of Bioresearch Monitoring ("BIMO"), the FDA Office of Device Evaluation placed an integrity hold on STAAR's TICL application. Over a two-year period STAAR took a number of corrective actions to address BIMO's concerns and to remove the integrity hold, including engaging an independent third party to conduct a 100% audit of patient records in the TICL clinical study, along with an audit of clinical systems to ensure accuracy and completeness of data before resubmitting the application. On July 21, 2009, the FDA notified STAAR that as a result of STAAR's corrective actions the FDA had removed the integrity hold on our application for approval of the TICL, and would resume its consideration of the application. During August and September 2009, the agency and STAAR resolved a number of questions related to the TICL supplement in an interactive process. On February 3, 2010, STAAR received a letter of deficiency from the FDA outlining additional questions. On August 2, 2010 we responded to the FDA's deficiency letter. Since that response, STAAR has been in dialogue with the agency, working interactively to resolve a series of follow-up questions. On April 22, 2011, STAAR responded to the most recent questions from the agency, which concerned the basis for an increase in the number of reported patient follow-up visits following the independent third party audit of the clinical data, and has responded to additional follow-up questions after that date. On November 29, 2011 STAAR received a letter from FDA further questioning the clinical data, specifically the inclusion of patient data that was obtained outside the study windows, requesting additional information on the lens design and a validation report for the Toric ICL power calculation software. STAAR has sent a preliminary response seeking clarification of the FDA's position on the study cohort. STAAR cannot predict when, or if, the FDA may grant approval of the Visian Toric ICL.

Medical Device Regulatory Compliance, Clinical Oversight and TICL Approval.

As discussed above under the caption "*Business — Regulatory Matters,*" STAAR's ability to develop, manufacture and distribute its products depends heavily on maintaining good standing with the FDA and other regulatory agencies. Based, in part, on the results of the FDA inspections of STAAR's California facilities in 2012 and 2010 and STAAR's Nidau, Switzerland facility in 2009, STAAR believes that it is substantially in compliance with the FDA's Quality System Regulations and Medical Device Reporting regulations. STAAR has invested significant resources in maintaining regulatory compliance and expects to continue to do so in the future.

Financing Strategy

STAAR reported net income in 2011 for the first time after more than ten years of reporting losses. Similarly, STAAR began generating cash from operations in 2009 after six consecutive years when our cash requirements exceeded the level of cash generated by operations. During those earlier periods STAAR has raised additional funds to support operations through sales of equity and debt securities. However, as cash flow improved in recent quarters, STAAR has avoided further financings and has operated exclusively on self-generated cash. As of December 30, 2011, STAAR has \$16.7 million in cash and cash equivalents.

STAAR believes its cash reserves, along with additional cash generated by operations, are sufficient to continue operations and to meet working capital needs for the foreseeable future. STAAR's need for working capital will depend in part on its degree of success in achieving and maintaining positive cash flow and earnings through the strategies described above under the caption "Strategy." If STAAR should need financing in the future, it cannot assure that such financing will be available on acceptable terms, if at all. STAAR's Japanese and Swiss subsidiaries have bank lines of credit in place for working capital purposes, but STAAR does not maintain such a credit line in the U.S.

In August 2011, STAAR filed a universal “shelf registration statement” with the Securities and Exchange Commission. The shelf registration statement covers the future public offering and sale of up to \$75 million in equity or debt securities or any combination of such securities. STAAR currently has no plans to issue any securities under the shelf registration statement. 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 a number of 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.

Results of Operations

The following table sets forth the percentage of total sales represented by certain items reflected in the Company’s consolidated statement of operations for the period indicated and the percentage increase or decrease in such items over the prior period.

	Percentage of Net Sales						Percentage Change	
	December 30, 2011	December 31, 2010		January 1, 2010		2011 vs. 2010	2010 vs. 2009	
Net sales	100.0%	100.0	%	100.0	%	14.2 %	7.6 %	
Cost of sales	32.5 %	36.2	%	38.7	%	2.6 %	0.7 %	
Gross profit	67.5 %	63.8	%	61.3	%	20.8 %	12.0 %	
General and administrative	23.8 %	26.9	%	29.4	%	6.1 %	(7.7)%	
Marketing and selling	28.2 %	31.3	%	30.0	%	3.2 %	12.3 %	
Research and development	9.3 %	10.4	%	11.5	%	2.5 %	(2.9)%	
Other general and administrative expenses	1.7 %	—		—		—	— *	
Operating income (loss)	4.4 %	(4.7)%		(9.6)%		— *	(46.7)%	
Total other expense, net	(0.1)%	(2.0)%		(1.7)%		(92.7)%	24.2 %	
Income (loss) before income taxes	4.3 %	(6.7)%		(11.3)%		— *	(36.0)%	
Provision for income taxes	2.2 %	0.8 %		2.3 %		— *	(62.6)%	
Income (loss) from continuing operations	2.1 %	(7.5)%		(13.6)%		— *	(40.4)%	
Income from discontinued operations, net of income taxes	0.0 %	7.6 %		1.4 %		— *	— *	
Net income (loss)	2.1 %	0.1 %		(12.2)%		— *	— *	

* Denotes change is greater than 100%

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

	% of Total	2011	% of Total	2010	% of Total	2009
IOL	43.9 %	\$27,547	50.1 %	\$27,550	51.5 %	\$26,299
ICL	51.1 %	32,074	44.2 %	24,300	41.2 %	21,046
Core Product Sales	95.0 %	59,621	94.3 %	51,850	92.7 %	47,345
Other	5.0 %	3,144	5.7 %	3,108	7.3 %	3,715
Total Sales	100.0 %	\$62,765	100.0 %	\$54,958	100.0 %	\$51,060

Net sales for 2011 were \$62.8 million, a 14.2% increase over the \$55.0 million reported in fiscal 2010. The increase in net sales was due to 15% increase in our core product sales (IOL and ICL). Core products represented 95.0% and 94.3% of the Company's total sales in fiscal year 2011 and 2010, respectively. Changes in foreign currency favorably impacted our net sales in 2011 by \$1.7 million.

Net sales for 2010 were \$55.0 million, a 7.6% increase over the \$51.1 million reported in fiscal 2009. The increase in net sales was due to 10% increase in our core product sales (IOL and ICL). Core products represented 94.3% and 92.7% of the Company's total sales in fiscal 2010 and 2009, respectively. Changes in foreign currency favorably impacted our net sales in 2010 by \$1.2 million.

Total IOL sales were \$27.5 million for fiscal 2011 and 2010, respectively. Increased sales of preloaded acrylic IOLs in China and Germany and Toric IOLs in the U.S. were offset by decreased Collamer and silicone IOL sales. Although IOL sales were essentially flat year over year, IOL margins were up 3% due to improved average selling prices, costs, and geographic mix. As an example, sales of our largest selling IOL, the preloaded silicone IOL, were down 1% year over year. However, preloaded IOL gross profit was up 3% due to higher sales in Japan where margins are high and lower sales in Europe where margins are low. IOL sales represented 43.9% and 50.1% of the Company's total sales in fiscal 2011 and 2010, respectively. Preloaded IOL sales represented 72% of total IOL sales in fiscal 2011, compared with 69% in fiscal 2010.

Total IOL sales for 2010 were \$27.6 million, a 4.8% increase over the \$26.3 million reported in fiscal 2009. The increase in IOL sales was due to a 28.2% increase in preloaded acrylic IOL sales primarily as a result of the full rollout of the product in Europe and also due to a 19.6% increase in nanoFLEX IOL sales in the U.S. These increases were partially offset by decreased sales of lower margin silicone IOLs. IOL sales represented 50.1% and 51.5% of the Company's total sales in fiscal 2010 and 2009, respectively. Preloaded IOL sales represented 69.3% of total IOL sales in fiscal 2010, compared with 66% in fiscal 2009.

Total ICL sales for 2011 were \$32.1 million, a 32% increase over the \$24.3 million reported in fiscal 2010. The increase in ICL sales resulted from a 35% increase in sales in our top ten refractive markets which comprised 85% of our total ICL sales in 2011. ICL sales represented 51% and 44% our total sales for fiscal years 2011 and 2010, respectively. Toric ICL sales represented 44% of total ICL sales, where approved, compared with 43% in fiscal 2010.

Total ICL sales for 2010 were \$24.3 million, a 15.5% increase over the \$21.0 million reported in fiscal 2009. The increase in ICL sales in 2010 is due to continued strong international sales as follows: India, up 57.2%, China, up 86.9%, Korea, up 13.4%, Lebanon, up 46.7%, Singapore, up 111.6%, France, up 24.3%, all other international markets, up 9.1%. U.S. ICL sales were down 4.2% due to a continued weak economy which significantly impacted the overall demand for refractive procedures in the U.S. ICL sales represented 44.2% and 41.2% of the Company's total sales in fiscal 2010 and 2009, respectively. Toric ICL sales represented 42.7% of total ICL sales, where approved, compared with 39.3% in fiscal 2009.

Other product sales, which have been deemphasized due to their low margins, were \$3.1 million in fiscal 2011 and 2010. Other product sales represented 5.0% and 5.7% of the Company's total sales in fiscal 2011 and 2010,

respectively.

Other product sales, which have been deemphasized due to their low margins, were \$3.1 million in fiscal 2010, a 16.3% decrease over the \$3.7 million in sales reported in fiscal 2009. Other product sales represented 5.7% and 7.3% of the Company's total sales in fiscal 2010 and 2009, respectively.

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

	2011	2010	2009
Gross Profit	\$42,369	\$35,076	\$31,323
Gross Profit Margin	67.5 %	63.8 %	61.3 %

Gross profit in fiscal 2011 was \$42.4 million compared with \$35.1 million in fiscal 2010. The increase in gross profit and gross profit margin was largely attributable to a higher mix of ICL sales and improved margins on IOL sales.

Gross profit in fiscal 2010 was \$35.1 million compared with \$31.3 million in fiscal 2009. Gross profit increased due to increased sales and decreased royalty expense which more than offset the increased cost of goods from higher sales. Gross profit margin increased from 61.3% in fiscal 2009 to 63.8% in fiscal 2010. The increase in gross profit margin is due to increased ICL sales and decreased other product sales and also due to decreased royalty expense. Royalty expense decreased by approximately \$738,000 as a result of the 2009 expiration of a patent licensed to STAAR.

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

	2011		2010		2009
General and Administrative Expense	\$14,932		\$14,778		\$15,009
Percentage of Sales	23.8	%	26.9	%	29.4

General and administrative expense in fiscal 2011 was \$14.9 million or 23.8% of sales, compared with \$14.8 million or 26.9% of sales in fiscal 2010. The increase in expense was primarily due to increased bonus accruals, travel and stock compensation expense largely offset by a \$700,000 decrease in severance costs.

General and administrative expense in fiscal 2010 was \$14.8 million or 26.9% of sales, compared with \$15.0 million or 29.4% of sales in fiscal 2009. The decrease in expense is primarily due to decreased legal expenses associated with litigation largely offset by a \$700,000 increase in severance costs.

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

	2011		2010		2009
Marketing and Selling Expense	\$17,726		\$17,176		\$15,300
Percentage of Sales	28.2	%	31.3	%	30.0

Marketing and selling expense in fiscal 2011 was \$17.7 million or 28.2% of sales, compared with \$17.2 million or 31.3% of sales in fiscal 2010. The increase in marketing and selling expense was due to increased headcount to support sales growth internationally and increased global promotional costs, partially offset by decreased costs in Australia resulting from the transition of the business to an independent distribution model. During 2012, the Company plans to add approximately 16 employees to support its ICL growth initiatives in the Asia Pacific, Europe, and the U.S. and to support global marketing efforts. This is expected to increase sales and marketing costs by approximately \$2 million.

Marketing and selling expense in fiscal 2010 was \$17.2 million or 31.3% of sales, compared with \$15.3 million or 30.0% of sales in fiscal 2009. The increase in marketing and selling expense is due to the investment in additional

direct sales representatives and increased promotional activities in the U.S. and also due to increased training and promotional activities as a result of the approval of the ICL in Japan. Despite the increase compared with 2009, marketing and selling expense in 2010 is 7% lower than 2008 on 10.4% higher sales.

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

	2011		2010		2009
Research and Development Expense	\$5,868		\$5,724		\$5,893
Percentage of Sales	9.3	%	10.4	%	11.5

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

Research and development expense in fiscal 2011 was \$5.9 million or 9.3% of sales, compared with \$5.7 million or 10.4% of sales in fiscal 2010. The increase in expense is due to increased headcount and salaries, travel, and patent legal expenses. The Company expects to spend approximately 9-10% of sales on research and development activities in 2012.

Research and development expense in fiscal 2010 was \$5.7 million or 10.4% of sales, compared with \$5.9 million or 11.5% of sales in fiscal 2009. The decrease compared with fiscal 2009 was primarily due to decreased depreciation expense and patent legal expenses.

The following table presents other general and administrative expenses (recoveries) for the fiscal years presented (dollars in thousands):

	2011	2010	2009
Other General and Administrative Expenses (Recoveries)	\$ 1,060	—	—
Percentage of Sales	1.7 %	—	—

Other general and administrative expenses in fiscal 2011 of \$1.1 million represent costs associated with the Company's plans to consolidate the manufacturing operations currently conducted in Switzerland, Japan, and Aliso Viejo, California, into its Monrovia, California location. These costs include consulting and tax services, accruals for asset retirement obligations, severance, and certain employee costs, including travel. The total cost of the project is expected to total approximately \$6 million and recorded over a four year period beginning 2011. Capital costs associated with the project are expected to total approximately \$2.4 million. During 2012, the Company expects to spend approximately \$2.0 million in expenses and \$2.0 million in capital for the project.

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

	2011	2010	2009
Other Expense, net	\$ 79	\$ 1,079	\$ 869
Percentage of Sales	(0.1 %)	(2.0 %)	(1.7 %)

Other expense, net generally relates to interest expense on notes payable and lease obligations, gains or losses on foreign currency transactions, royalty income, and fair value adjustments of outstanding warrants. The table below summarizes the year over year changes in other expense, net (in thousands).

	Favorable (Unfavorable)
	2010
	2011 v. 2010 v.
	2009
Interest income	(\$ 12) (\$ 24)

Edgar Filing: STAAR SURGICAL CO - Form 10-K

Interest expense (1)	373	421
Loss on extinguishment of note payable (1)	267	(267)
Exchange gains (losses)	173	(211)
Royalty income	137	(3)
Fair value adjustment of warrants (2)	25	(103)
Other	35	(23)
Net decrease in other expense, net	\$ 1,000	\$ (210)

(1) The decrease in interest expense was primarily due to the repayment of the Broadwood note in fiscal 2010. The loss on early extinguishment of note payable was the result of early repayment of the Broadwood note.

(2) Relates to the fair value of 70,000 warrants issued to Broadwood on March 21, 2007 at \$6.00 per share. The warrants expire on March 21, 2013.

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

	2011	2010	2009
Provision for Income Taxes	\$1,356	\$432	\$1,154

Our provision for income taxes increased from 2011 to 2010, as a result of higher taxable income in jurisdictions where we pay tax. Our effective tax rate for 2011 was 50%. We expect this to improve to between 40% and 45% during 2012. We do not expect to begin to see the tax benefits associated with our manufacturing consolidation project until 2014 when manufacturing is projected to be fully consolidated.

Our provision for income taxes decreased from 2009 to 2010, primarily as a result of lower taxable income in jurisdictions where we pay tax.

See Critical Accounting Policies included later in this Item 7 for additional information about our provision for income taxes.

A reconciliation of the federal statutory income tax rate to our effective tax rate is set forth in Note 12 of Notes to the Consolidated Financial Statements included in Item 8 of this Annual Report on Form 10-K.

Liquidity and Capital Resources

We have historically financed our operations primarily through the issuance of common stock and by relying on equipment and other commercial financing. During 2012, and for the foreseeable future, we will be highly dependent on our net product revenue to supplement our current liquidity and fund our operations. We may, in the future elect, to supplement this with further debt or commercial borrowing

The Company believes its current cash balances coupled with cash flow from operating activities will be sufficient to meet its working capital requirements for the foreseeable future, including cost and capital associated with the Company's plans to consolidate manufacturing. STAAR's need for working capital, and the terms on which financing may be available, will depend in part on its degree of success in maintaining positive cash flow through the strategies described above under the caption "Strategy."

Our financial condition as of December 30, 2011 for each of the years indicated included the following (in millions):

	2011	2010	2009	2011 v 2010	2010 v. 2009
Cash and cash equivalents	\$16.6	\$9.4	\$6.3	\$ 7.2	\$ 3.1
Current assets	\$38.7	\$30.0	\$40.4	\$ 8.7	\$ (10.4)
Current liabilities	14.0	13.4	27.0	0.6	13.6
Working capital	\$24.7	\$16.6	\$13.4	\$ 8.1	\$ 3.2

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

Net cash provided by (used in) operating activities was \$5.3 million, (\$4.4 million) and \$1.4 million for fiscal year 2011, 2010, and 2009 respectively. For 2011, net cash provided by operating activities consisted of net income of \$1.3 million, \$4.6 million in non-cash activities and \$0.6 million used for working capital. For 2010, the use of cash from operations included the following significant items: payment of \$4.0 million related to the global settlement of the legal judgments and \$0.6 million used in the operating activities of discontinued operations of our previously disposed German subsidiary Domilens GmbH, payment of \$0.4 million of Domilens transaction related costs, and approximately \$0.8 million interest paid for the Broadwood note.

Net cash provided by (used in) investing activities was (\$0.9 million), \$18.8 million and (\$7.6 million) for fiscal year 2011, 2010, and 2009 respectively. Net cash used in investing activities for 2011 was due to acquisition of property, plant and equipment. For 2010, net cash provided by investing activities in was due to the \$11.8 million net cash proceeds from the sale of Domilens in March 2010 and the release of the \$7.4 million restricted deposit, including interest, by the Court and offset by \$0.4 million for acquisition of property and equipment. For 2009, net cash used in investing activities includes the \$7.4 million posted as a restricted deposit, including reinvested interest, held as a litigation appeal bond and \$0.6 million in acquisition of property, plant and equipment.

Net cash provided by (used by) financing activities was \$2.8 million, (\$11.5 million), and \$7.4 million for fiscal year 2011, 2010 and 2009, respectively. For 2011, net cash provided by financing activities consisted of \$3.3 million in proceeds from exercise of stock options, partially offset by \$0.5 million in capital lease repayment. For 2010, net cash used by financing activities consisted of \$5 million principal payment on a promissory note held by Broadwood Partners, L.P., the \$6.8 million cash redemption of all of our then outstanding Series A preferred shares, and the \$0.8 million repayment of principal on our capital lease obligations, partially offset by \$1.1 million in cash proceeds from stock option exercises. For 2009, net cash provided by financing activities was primarily due to \$8.5 million in proceeds from the sale of STAAR common stock in order to fund the Parallax bond, partially offset by \$1.0 million repayment of principal on capital lease obligations.

Accounts receivable was \$9.1 million as of December 30, 2011 and \$8.2 million as of December 31, 2010. Days' Sales Outstanding ("DSO") was 50 days in 2011 and 52 days in 2010. The Company expects to maintain DSO within a range of 50 to 55 days during the course of fiscal 2012.

Inventories at the end of fiscal 2011 and 2010 were \$10.9 million and \$10.5 million, respectively. Days' inventory on hand ("DOH") was 129 days in 2011 and 116 days in 2010 based on finished goods, including consignment inventory.

Shelf Registration

In August 2011, STAAR filed a universal "shelf registration statement" with the Securities and Exchange Commission. The shelf registration statement covers the future public offering and sale of up to \$75 million in equity or debt securities or any combination of such securities. STAAR currently has no plans to issue any securities under the shelf registration statement. 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 a number of 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, Contractual Obligations and Commitments

Credit Facilities

The Company has credit facilities with different lenders to support operations as detailed below.

Line of Credit

The Company's wholly owned Japanese subsidiary, STAAR Japan, has an agreement, as amended on June 30, 2009, with Mizuho Bank which provides for borrowings of up to 300,000,000 Yen (approximately \$3.9 million based on the rate of exchange on December 30, 2011), at an interest rate equal to the Tokyo short-term prime interest rate (approximately 1.475% as of December 30, 2011) plus 1.125% and may be renewed annually (the current line expires on April 2, 2012). The credit facility is not collateralized. The Company had 200,000,000 Yen outstanding on the line of credit as of December 30, 2011 and December 31, 2010, (approximately \$2.6 million and \$2.5 million based on the foreign exchange rates on December 30, 2011 and December 31, 2010) and 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. While no assurance can be given, the Company believes the credit line will be renewed in fiscal 2012.

In August 2010, the Company's wholly owned Swiss subsidiary, STAAR Surgical AG, entered into a credit agreement with Credit Suisse (the "Bank"). The credit agreement provides for borrowings of up to 1,000,000 CHF (Swiss Francs) (\$1,060,000 at the rate of exchange on December 30, 2011), 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 credit agreement is automatically renewed on an annual basis based on the same terms assuming there is no default. The credit agreement may be terminated by either party at any time in accordance with its general terms and conditions. The credit facility 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 credit 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 AG's independent auditors' report. There were no borrowings outstanding as of December 30, 2011 and the full amount of the line was available for borrowing.

Covenant Compliance

The Company is in compliance with the covenants of its credit facilities and lines of credit as of December 30, 2011.

Contractual Obligations

The following table represents the Company's known contractual obligations as of December 30, 2011 (in thousands):

Contractual Obligations	Payments Due by Period				More Than 5 Years
	Total	1 Year	2-3 Years	4-5 Years	
Line of credit	\$2,580	\$2,580	\$—	\$—	\$—
Capital lease obligations	1,912	947	926	39	—
Operating lease obligations	9,005	2,307	3,880	2,818	—
Pension obligations	1,971	110	256	338	1,267
Severance	1,474	437	1,037	—	—
Open purchase orders	141	141	—	—	—
Total	\$17,083	\$6,522	\$6,099	\$3,195	\$1,267

Critical Accounting Policies

The preparation of financial statements in accordance with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of sales and expenses during the reporting period. On an on-going basis, we evaluate our estimates, including those related to revenue recognition, allowances for doubtful accounts and sales return, inventory reserves and income taxes, among others. Our estimates are based on historical experiences, market trends and financial forecasts and projections, and on various other assumptions that management believes are reasonable under the circumstances and at that certain point in time. Actual results may differ, significantly at times, from these if actual conditions differ from our assumptions.

We believe the following represent our critical accounting policies.

Revenue Recognition and Accounts Receivable. We recognize revenue when realized or realizable and earned, which is when the following criteria are met: persuasive evidence of an arrangement exists; delivery has occurred; the sale price is fixed and determinable; and collectability is reasonably assured. The Company records revenue from non-consignment product sales when title and risk of ownership has been transferred, which is typically at shipping point, except for our STAAR Japan subsidiary, which is typically recognized when the product is received by the customer. STAAR Japan does not have significant deferred revenues as delivery to the customer is generally made within the same or the next date of shipment. Our products are marketed to ophthalmic surgeons, hospitals, ambulatory surgery centers or vision centers, and distributors. IOLs may be offered to surgeons and hospitals on a consignment basis. We maintain title and risk of loss on consigned inventory. We recognize revenue for consignment inventory when we are informed the IOL has been implanted and not upon shipment to the surgeon.

We believe our revenue recognition policies are appropriate. We present sales tax we collect from our customers on a net basis (excluded from our revenues).

We ship ICLs only for use by surgeons who have already been certified, or for use in scheduled training surgeries.

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

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

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

Stock-Based Compensation. We account for the issuance of stock options to employees and directors by estimating the fair value of options and warrants issued using the Black-Scholes pricing model. This model's calculations include the exercise price, the market price of shares on grant date, risk-free interest rates, expected term of the option or warrant, expected volatility of our stock and expected dividend yield. The amounts recorded in the financial statements for share-based expense could vary significantly if we were to use different assumptions.

Accounting for Warrants. We account for the issuance of company derivative equity instruments such as the warrants, in accordance with ASC 815-40. We agreed to use our best efforts to register and maintain registration of the common shares underlying certain warrants (the "Warrant Shares") that were issued by us with debt instruments, so that the warrant holder may freely sell the Warrant Shares if the warrant is exercised, and we agreed that in any event we would secure effective registration within a certain time period after issuance (typically up to five months from issuance). In addition, while the relevant warrant agreement does not require cash settlement if we do not maintain continuous registration of certain Warrant Shares, the agreement does not specifically preclude cash settlement. As a result ASC 815-40 requires us to assume that in the absence of continuous effective registration we may be required to settle some of these warrants for cash when they are exercised. Accordingly, our agreement to register and maintain registration of certain Warrant Shares without express terms for settlement in the absence of continuous effective registration is presumed to create a liability to settle these warrants in cash, requiring liability classification. We have issued other warrants under another agreement that expressly provides that if we fail to satisfy registration requirements we will be obligated only to issue additional common stock as the holder's sole remedy, with no possibility of settlement in cash. In this circumstance, we account for those warrants as equity because additional shares are the only form of settlement available to the holder. We use the Black-Scholes option pricing model as the valuation model to estimate the fair value of all warrants. We evaluate the balance sheet classification of the warrants during each reporting period. Expected volatilities are based on historical volatility of our stock. The expected life of the warrant is determined by the amount of time remaining on the original six-year term of the relevant warrant agreement. The risk-free rate of return for periods within the contractual life of the warrant is based on the U.S. Treasury yield curve in effect at each reporting period. Any gains or losses resulting from the changes in fair value of the warrants classified as a liability from period to period are included as an increase or decrease of other income (expense). The warrants that are accounted for as equity are only valued on the issuance date and not subsequently revalued.

Income Taxes. We account for income taxes under the asset and liability method, whereby deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. We evaluate the need to establish a valuation allowance for deferred tax assets based on the amount of existing temporary differences, the period in which they are expected to be recovered and expected levels of taxable income. A valuation allowance to reduce deferred tax assets is established when it is "more likely than not" that some or all of the deferred tax assets will not be realized.

We expect to continue to maintain a full valuation allowance on future tax benefits until, and if, an appropriate level of profitability is sustained, or we are able to develop tax strategies that would enable us to conclude that it is more likely than not that a portion of our deferred tax assets would be realizable.

In the normal course of business, the Company is regularly audited by federal, state and foreign tax authorities, and is periodically challenged regarding the amount of taxes due. These challenges include questions regarding the timing and amount of deductions and the allocation of income among various tax jurisdictions. We believe that our tax positions comply with applicable tax law and intend to defend our positions. Our effective tax rate in a given financial statement period could be impacted if we prevailed in matters for which reserves have been established, or were required to pay amounts in excess of established reserves.

Inventories. We provide estimated inventory allowances for excess, slow moving, expiring and obsolete inventory as well as inventory whose carrying value is in excess of net realizable value. These reserves are based on current assessments about future demands, market conditions and related management initiatives. If market conditions and actual demands are less favorable than those projected by management, additional inventory write-downs may be required. We value our inventory at the lower of cost or net realizable market values. We regularly review inventory quantities on hand and record a provision for excess and obsolete inventory based primarily on the expiration of products with a shelf life of less than four months, estimated forecasts of product demand and production requirements for the next twelve months. Several factors may influence the realizability of our inventories, including decisions to exit a product line, technological change and new product development. These factors could result in an increase in the amount of obsolete inventory quantities on hand. Additionally, estimates of future product demand may prove to be inaccurate, in which case the provision required for excess and obsolete inventory may be understated or overstated. If in the future, we determine that our inventory was overvalued, we would be required to recognize such costs in cost of sales at the time of such determination. Likewise, if we determine that our inventory was undervalued, cost of sales in previous periods could have been overstated and we would be required to recognize such additional operating income at the time of sale. While such inventory losses have historically been within our expectations and the provisions established, we cannot guarantee that we will continue to experience the same loss rates that we have in the past. Therefore, although we make every effort to ensure the accuracy of forecasts of future product demand, including the impact of planned future product launches, any significant unanticipated changes in demand or technological developments could have a significant impact on the value of our inventory and our reported operating results.

Impairment of Long-Lived Assets. Intangible and other long lived-assets are reviewed for impairment whenever events such as product discontinuance, plant closures, product dispositions or other changes in circumstances indicate that the carrying amount may not be recoverable. Certain factors which may occur and indicate that an impairment exists include, but are not limited to the following: significant underperformance relative to expected historical or projected future operating results; significant changes in the manner of the Company's 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. In the event that 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 a number of assumptions and projections, which could include, but would not be limited to, future revenues, earnings and the probability of certain outcomes and scenarios. Our policy is consistent with current accounting guidance as prescribed by ASC 360-10-35, *Accounting for the Impairment or Disposal of Long-Lived Assets*.

Goodwill. Goodwill, which has an indefinite life, is not amortized, but instead is subject to periodic testing for impairment. Intangible assets determined to have definite lives are amortized over their remaining useful lives. Goodwill is tested for impairment on an annual basis or between annual tests if an event occurs or circumstances change that would reduce the fair value of a reporting unit below its carrying amount. Certain factors which may occur and indicate that impairment exists include, but are not limited to the following: significant underperformance relative to expected historical or projected future operating results; significant changes in the manner of our use of the underlying assets; and significant adverse industry or market economic trends. In the event that the carrying value of assets is determined to be unrecoverable, we would estimate the fair value of the reporting unit and record

an impairment charge for the excess of the carrying value over the fair value. The estimate of fair value requires management to make a number of assumptions and projections, which could include, but would not be limited to, future revenues, earnings and the probability of certain outcomes and scenarios, including the use of experts.

Definite-Lived Intangible Assets. We also have other intangible assets mainly consisting of patents and licenses, developed technologies and customer relationships, with a gross book value of \$14.1 million and accumulated amortization of \$11.2 million as of December 30, 2011. We capitalize the cost of acquiring patents and licenses. We acquired certain customer relationships and developed technologies in the acquisition of our STAAR Japan subsidiary which was completed on December 29, 2007. Amortization is computed on the straight-line basis over the estimated useful lives of the assets, since the pattern in which the economic benefits realized cannot be reasonably determined, which are based on legal, contractual and other provisions, and range from 10 to 21 years for patents and licenses, 10 years for customer relationships and 3 to 10 years for developed technology. We review intangible assets for impairment in the assessment discussed above regarding *Impairment of Long-Lived Assets*.

Employee Defined Benefit Plans. We have maintained a passive pension plan (the “Swiss Plan”) covering employees of its Swiss subsidiary. The Company concluded that the features of the Swiss Plan conform to the features of a defined benefit plan. As a result, we adopted the recognition and disclosure requirements of ASC 715-20-65 Transition Guidance, *Employers’ Accounting for Defined Benefit Pension and Other Postretirement Plans*.

In connection with our acquisition of the remaining interest in STAAR Japan, Inc., we assumed the net pension liability under STAAR Japan's noncontributory defined benefit pension plan substantially covering all of the employees of STAAR Japan. STAAR Japan adopted the recognition and disclosure requirements of ASC 715-30 on December 29, 2007, the date of the acquisition.

ASC 715-30 requires recognition of the funded status, or difference between the fair value of plan assets and the projected benefit obligations of the pension plan on the statement of financial position with a corresponding adjustment to accumulated other comprehensive income. If the projected benefit obligation exceeds the fair value of plan assets, then that difference or unfunded status represents the pension liability. We record a net periodic pension cost in the consolidated statement of operations. The liabilities and annual income or expense of both plans are determined using methodologies that involve several actuarial assumptions, the most significant of which are the discount rate, and the expected long-term rate of asset return (based on the market-related value of assets). The fair values of plan assets are determined based on prevailing market prices. The amounts recorded in the financial statements pertaining to our employee defined benefit plans could vary significantly if we were to use different assumptions.

Foreign Exchange

Management does not believe that the fluctuation in the value of the dollar in relation to the currencies of its suppliers or customers in the last three fiscal years had 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 engage in hedging transactions to offset changes in currency or fluctuations in foreign currencies.

Inflation

Management believes inflation has not had a significant impact on our operations during the past three years.

Recent Accounting Pronouncements

See Item 8 of Part II, “Financial Statements and Supplementary Data – Note 1 – Significant Accounting Policies – Recent Accounting Pronouncements.”

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

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

Interest rate risk. As of December 30, 2011, STAAR had \$2.6 million of foreign debt. Our \$2.6 million of foreign debt bears an interest rate that is equal to the Tokyo short-term prime interest rate (approximately 1.475% as of December 30, 2011) plus 1.125%. Thus, our interest expense would fluctuate with any change in the prime interest rate. If the Tokyo prime rate were to increase or decrease by 1% for the year, our annual interest expense would increase or decrease by approximately \$26,000 based on the exchange rate in effect at December 30, 2011.

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. Cost of goods sold and selling, general, and administrative expenses that correspond with these sales are largely denominated in the same currency, thereby limiting our transaction risk exposure.

Our international subsidiaries operate in and are net recipients of currencies other than the U.S. dollar and, as a result, our sales benefit from a weaker dollar and are reduced by a stronger dollar relative to major currencies worldwide (primarily, the Euro and the Japanese Yen). Accordingly, changes in exchange rates, and particularly the strengthening of the U.S. Dollar, may negatively affect our consolidated sales and gross profit as expressed in U.S. dollars. Additionally, expenses of our Swiss subsidiary are largely denominated in Swiss Francs and a strong Swiss Franc negatively impacts our earnings. Fluctuations during any given reporting period result in the re-measurement of our foreign currency denominated cash, receivables, and payables, generating currency transaction gains or losses and are reported in total other expenses in our consolidated statements of operations. In the normal course of business, we also face risks that are either non-financial or non-quantifiable. Such risks include those set forth in “Item 1A. — Risk Factors.”

Item 8. Financial Statements and Supplementary Data

Financial Statements and the Reports 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. Page F-3 of this Annual Report on Form 10-K sets forth the report of BDO USA, LLP, our independent registered public accounting firm, regarding its audit of STAAR’s internal control over financial reporting. 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 STAAR Surgical Company and its subsidiaries (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 30, 2011, 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.

Management's Annual Report on Internal Control over Financial Reporting

The Company's management, including our Chief Executive Officer and Chief Financial Officer, 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 STAAR Surgical Company and its subsidiaries (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 30, 2011, based on the criteria for effective internal control described in Internal Control — Integrated Framework 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 30, 2011.

Changes in Internal Control over Financial Reporting

There was no change during the fiscal quarter ended December 30, 2011 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

Compensatory Arrangements of Certain Officers:

The following elements of compensation have been approved by the Board of Directors of STAAR Surgical Company, with the approval effective on March 2, 2012, except for salary increases which are effective on March 26, 2012.

For the Chief Executive Officer, Chief Financial Officer and named Executive Officers listed below the compensation was awarded as follows:

New Salary and Bonuses for 2011 Performance

Name and Title	New Salary (1)	Bonus
Barry Caldwell President and CEO	\$475,000	\$290,000
Deborah Andrews Vice President and Chief Financial Officer	\$275,000	\$105,000
Hans Blickensdoerfer		

Edgar Filing: STAAR SURGICAL CO - Form 10-K

President EMEA and Latin America Robin Hughes	\$326,993	\$130,000
Global Vice President Marketing Philippe Subrin	\$275,000	\$110,000
Vice President Switzerland Operations	\$288,308	\$87,750

- (1) The new salary rates become effective on March 26, 2012.

Long-Term Equity Compensation

Name and Title	Performance Accelerated Restricted Shares of Common Stock (1)	Stock Options
		(2)
Barry Caldwell President and CEO	15,000	40,000
Deborah Andrews Vice President and Chief Financial Officer	7,500	20,000
Hans Blickensdoerfer President EMEA and Latin America	7,500	20,000
Robin Hughes Global Vice President Marketing	7,500	20,000
Philippe Subrin Vice President Switzerland Operations	7,500	20,000

The PARS may not be sold or transferred until vested on March 12, 2015, unless achievement of specified (1) performance criteria results in accelerated vesting. Until vested the shares are subject to forfeiture if service to the Company terminates.

(2) The options are exercisable for common stock at a price of \$11.00 per share, vest in three equal installments on March 2, 2013, March 2, 2014, and March 2, 2015, and expire on March 1, 2022.

In total, the Board of Directors approved aggregate awards of cash bonuses for 2011 performance to STAAR employees equaling \$1.5 million to be distributed to approximately 32 employees. The Company accrued the total cash bonuses as an expense during the fiscal year that ended December 30, 2011, and that expense is reflected in the consolidated financial statements of the Company in this 10-K.

PART III

Item 10. Directors and Executive Officers and Corporate Governance

The information required by this item is incorporated herein by reference to the section entitled “Proposal One — Election of Directors” contained in the proxy statement (the “Proxy Statement”) for the 2012 annual meeting of stockholders to be filed with the Securities and Exchange Commission within 120 days of the close of the fiscal year ended December 30, 2011.

Item 11. Executive Compensation

The information required by this item is incorporated herein by reference to the section entitled “Proposal One — Election of Directors” contained in the Proxy Statement.

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

The information required by this item is incorporated herein by reference to the section entitled “General Information — Security Ownership of Certain Beneficial Owners and Management” and “Proposal One — Election of Directors” contained in the Proxy Statement.

Item 13. Certain Relationships and Related Transactions and Director Independence

The information required by this item is incorporated herein by reference to the section entitled “Proposal One — Election of Directors” contained in the Proxy Statement.

Item 14. Principal Accountant Fees and Services

The information required by this item is incorporated herein by reference to the section entitled “Proposal Two — Ratification of the Appointment 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	
Reports of Independent Registered Public Accounting Firm	F-2
Consolidated Balance Sheets	F-4
Consolidated Statements of Operations	F-5
Consolidated Statements of Changes in Stockholders' Equity and Comprehensive Income	F-6
Consolidated Statements of Cash Flows	F-7
Notes to Consolidated Financial Statements	F-8
(2) Schedules required by Regulation S-X are filed as an exhibit to this report:	
I. Independent Registered Public Accounting Firm Report on Schedule	
II. Schedule II — Valuation and Qualifying Accounts and Reserves	

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

(3) Exhibits

- 3.1 Certificate of Incorporation, as amended to date(1)
- 3.2 By-laws, as amended to date(2)
- †4.3 1998 STAAR Surgical Company Stock Plan, adopted April 17, 1998(3)
- 4.4 Form of Certificate for Common Stock, par value \$0.01 per share(4)
- †4.5 Amended and Restated 2003 Omnibus Equity Incentive Plan and form of Option Grant and Stock Option Agreement(5)
- 10.3 Indenture of Lease dated September 1, 1993, by and between the Company and FKT Associates and First through Third Additions Thereto(6)
- 10.4 Second Amendment to Indenture of Lease dated September 21, 1998, between the Company and FKT Associates(6)
- 10.5 Third Amendment to Indenture of Lease dated October 13, 2003, by and between the Company and FKT Associates(7)
- 10.6 Fourth Amendment to Indenture of Lease dated September 30, 2006, by and between the Company and FKT Associates(1)
- 10.7 Indenture of Lease dated October 20, 1983, between the Company and Dale E. Turner and Francis R. Turner and First through Fifth Additions Thereto(8)
- 10.8 Sixth Lease Addition to Indenture of Lease dated October 13, 2003, by and between the Company and Turner Trust UTD Dale E. Turner March 28, 1984(7)

Edgar Filing: STAAR SURGICAL CO - Form 10-K

- 10.9 Seventh Lease Addition to Indenture of Lease dated September 30, 2006, by and between the Company and Turner Trust UTD Dale E. Turner March 28, 1984(1)
- 10.10 Amendment No. 1 to Standard Industrial/Commercial Multi-Tenant Lease dated January 3, 2003, by and between the Company and California Rosen LLC(7)
- 10.11 Lease Agreement dated July 12, 1994, between STAAR Surgical AG and Calderari and Schwab AG/SA(9)
- 10.12 Supplement #1 dated July 10, 1995, to the Lease Agreement of July 12, 1994, between STAAR Surgical AG and Calderari and Schwab AG/SA(9)
- 10.13 Supplement #2 dated August 2, 1999, to the Lease Agreement of July 12, 1994, between STAAR Surgical AG and Calderari and Schwab AG/SA(9)
- 10.20 Patent License Agreement, dated January 1, 1996, with Eye Microsurgery Intersectoral Research and Technology Complex(10)
- †10.42 Form of Indemnification Agreement between the Company and certain officers and directors(9)
- 10.59 Standard Industrial/Commercial Multi Tenant Lease — Gross dated October 6, 2005, entered into between the Company and Z & M LLC(11)
- 10.64 Warrant Agreement between STAAR Surgical Company and Broadwood Partners, L.P., dated March 21, 2007. (12)
- †10.66 Executive Employment Agreement by and between the Company and Barry G. Caldwell, dated as of November 27, 2007. (13)
- 10.69 Warrant Agreement between STAAR Surgical Company and Broadwood Partners, L.P., dated December 14, 2007.(14)

- †10.70 Amended and Restated Executive Employment Agreement by and between the Company and Barry G. Caldwell, dated December 31, 2008.(15)
- †10.76 Employment Agreement effective November 22, 2002 by and between the Company and Deborah Andrews.(16)
- †10.77 Letter of the Company dated April 11, 2007 to Deborah Andrews, Vice President and Chief Financial Officer, regarding compensation.(16)
- †10.79 Employment Agreement, dated December 16, 2004, by and between the Company and Hans Blickensdoerfer.(16)
- 10.80 Credit Agreement between STAAR Japan Inc. and Mizuho Bank Inc., dated October 31, 2007.(17)
- 10.81 Amended Credit Agreement between STAAR Japan Inc. and Mizuho Bank Ltd., dated June 30, 2009.(17)
- 10.82 Basic Agreement on Unsterilized Intraocular Lens Sales Transactions between Canon Staar Co., Inc. and Nidek Co., Ltd., dated May 23, 2005.(18)
- 10.83 Basic Agreement on Injector Product Sales Transactions between Canon Staar Co., Inc. and Nidek Co., Ltd., dated May 23, 2005.(18)
- 10.84 Memorandum of Understanding Concerning Basic Agreements for Purchase and Sale between STAAR Japan Inc. and Nidek Co., Ltd., dated December 25, 2008.(18)
- 10.85 Acrylic Preset supply Warranty Agreement between STAAR Japan Inc. and Nidek Co., Ltd., dated December 25, 2008.(18)
- 10.86 Framework Agreement for Loans between Credit Suisse and STAAR Surgical AG, dated August 12, 2010. (19)
- †10.88 Form of Executive Severance Agreement(20)
- †10.89 Form of Executive Change In Control Agreement(20)
- 14.1 Code of Ethics(9)
- 21.1 List of Significant 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*

*Filed herewith

†Management contract or compensatory plan or arrangement

All schedules and or exhibits have been omitted. Any omitted schedule or exhibit will be furnished supplementally to the Securities and Exchange Commission upon request.

- (1) Incorporated by reference to the Company's Annual Report on Form 10-K, for the year ended December 28, 2007, as filed on March 12, 2008.
- (2) Incorporated by reference from the Company's Current Report on Form 8-K, as filed on May 23, 2006.
- (3) Incorporated by reference to the Company's Proxy Statement for its Annual Meeting of Stockholders held on May 29, 1998, filed on May 1, 1998.
- (4) Incorporated by reference to Exhibit 4.1 to Amendment No. 1 to the Company's Registration Statement on Form 8-A/A, as filed on April 18, 2003.
- (5)

Edgar Filing: STAAR SURGICAL CO - Form 10-K

Incorporated by reference to the Company's Proxy Statement for its Annual Meeting of Stockholders held on May 19, 2010, filed on April 9, 2010.

- (6) Incorporated by reference to the Company's Annual Report on form 10-K for the year ended December 29, 2000, as filed on March 9, 2001.
- (7) Incorporated by reference to the Company's Annual Report on Form 10-K, for the year ended January 2, 2004, as filed on March 17, 2004.
- (8) Incorporated by reference from the Company's Annual Report on Form 10-K, for the year ended January 2, 1998, as filed on April 1, 1998.
- (9) Incorporated by reference from the Company's Annual Report on Form 10-K, for the year ended December 31, 2004, as filed on March 30, 2005.
- (10) Incorporated by reference to the Company's Annual Report on form 10-K for the year ended January 3, 1997, as filed on April 2, 1997.
- (11) Incorporated by reference to the Company's Annual Report on form 10-K for the year ended December 29, 2000, as filed on March 28, 2002.

- (11) Incorporated by reference to the Company's Quarterly Report on Form 10-Q for the period ended September 30, 2005, as filed on November 9, 2005.
- (12) Incorporated by reference to the Company's Current Report on form 8-K filed on March 21, 2007.
- (13) Incorporated by reference to the Company's Current Report on Form 8-K filed on December 4, 2007.
- (14) Incorporated by reference to the Company's Current Report on form 8-K filed on December 17, 2007.
- (15) Incorporated by reference to the Company's Current Report on Form 8-K filed on January 8, 2009.
- (16) Incorporated by reference to the Company's Current Report on Form 8-K filed on October 1, 2009.
- (17) Incorporated by reference to the Company's Quarterly Report on Form 10-Q for the period ended October 2, 2009, as filed on November 12, 2009.
- (18) Incorporated by reference to the Company's Annual Report on Form 10-K for the year ended January 1, 2010.
- (19) Incorporated by reference to the Company's Quarterly Report on Form 10-Q for the period ended October 1, 2010, as filed on November 10, 2010.
- (20) Incorporated by reference to the Company's Quarterly Report on Form 10-Q for the period ended September 30, 2011, as filed on November 2, 2011.

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: March 8, 2012 By: /s/ Barry G. Caldwell
 Barry G. Caldwell
 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
<u>/s/ Barry G. Caldwell</u> Barry G. Caldwell	President, Chief Executive Officer and Director (principal executive officer)	March 8, 2012
<u>/s/ Deborah Andrews</u> Deborah Andrews	Vice President, Chief Financial Officer (principal accounting and financial officer)	March 8, 2012
<u>/s/ Don Bailey</u> Don Bailey	Chairman of the Board, Director	March 8, 2012
<u>/s/ Donald Duffy</u> Donald Duffy	Director	March 8, 2012
<u>/s/ John C. Moore</u> John C. Moore	Director	March 8, 2012
<u>/s/ David Morrison</u> David Morrison	Director	March 8, 2012

/s/ Richard A. Meier

Director

March 8, 2012

Richard A. Meier

/s/ Mark B. Logan

Director March 8, 2012

Mark B. Logan

STAAR SURGICAL COMPANY AND SUBSIDIARIES

CONSOLIDATED FINANCIAL STATEMENTS

Years Ended December 30, 2011, December 31, 2010, and January 1, 2010

TABLE OF CONTENTS

Report of Independent Registered Public Accounting Firm	F-2
Report of Independent Registered Public Accounting Firm	F-3
Consolidated Balance Sheets at December 30, 2011 and at December 31, 2010	F-4
Consolidated Statements of Operations for the years ended December 30, 2011, December 31, 2010, and January 1, 2010	F-5
Consolidated Statements of Stockholders' Equity and Comprehensive Income (Loss) for the years ended December 30, 2011, December 31, 2010, and January 1, 2010	F-6
Consolidated Statements of Cash Flows for the years ended December 30, 2011, December 31, 2010, and January 1, 2010	F-7
Notes to Consolidated Financial Statements	F-8
Report on Schedule II – Valuation and Qualifying Accounts and Reserves	F-35
F-1	

STAAR SURGICAL COMPANY AND SUBSIDIARIES

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Stockholders

STAAR Surgical Company

Monrovia, CA

We have audited the accompanying consolidated balance sheets of STAAR Surgical Company and Subsidiaries (“the Company”) as of December 30, 2011 and December 31, 2010, and the related consolidated statements of operations, stockholders’ equity and comprehensive income (loss), and cash flows for each of the three years in the period ended December 30, 2011. These financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of STAAR Surgical Company and Subsidiaries as of December 30, 2011 and December 31, 2010, and the consolidated results of their operations and their cash flows for each of the three years in the period ended December 30, 2011, 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), STAAR Surgical Company and Subsidiaries’ internal control over financial reporting as of December 30, 2011, based on criteria established in *Internal Control – Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) and our report dated March 8, 2012 expressed an unqualified opinion thereon.

/s/ BDO USA, LLP

Los Angeles, California

March 8, 2012

F-2

STAAR SURGICAL COMPANY AND SUBSIDIARIES

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Stockholders

STAAR Surgical Company

Monrovia, CA

We have audited STAAR Surgical Company and Subsidiaries' internal control over financial reporting as of December 30, 2011, based on criteria established in *Internal Control – Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). STAAR Surgical Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Item 9A, Management's Annual Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). 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.

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.

Edgar Filing: STAAR SURGICAL CO - Form 10-K

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.

In our opinion, STAAR Surgical Company and Subsidiaries maintained, in all material respects, effective internal control over financial reporting as of December 30, 2011, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of STAAR Surgical Company and Subsidiaries as of December 30, 2011 and December 31, 2010, and the related consolidated statements of operations, stockholders' equity and comprehensive income (loss), and cash flows for each of the three years in the period ended December 30, 2011 and our report dated March 8, 2012 expressed an unqualified opinion thereon.

/s/ BDO USA, LLP

Los Angeles, California

March 8, 2012

F-3

STAAR SURGICAL COMPANY AND SUBSIDIARIES**CONSOLIDATED BALANCE SHEETS****December 30, 2011 and December 31, 2010**

	2011	2010	
	(In thousands, except par value amounts)		
ASSETS			
Current assets:			
Cash and cash equivalents	\$ 16,582	\$ 9,376	
Restricted cash	129	133	
Accounts receivable trade, net	9,089	8,219	
Inventories, net	10,933	10,543	
Prepays, deposits and other current assets	1,921	1,715	
Total current assets	38,654	29,986	
Property, plant and equipment, net	4,222	3,732	
Intangible assets, net	2,989	3,672	
Goodwill	1,786	1,786	
Deferred income taxes	152	202	
Other assets	1,203	1,207	
Total assets	\$ 49,006	\$ 40,585	
LIABILITIES AND STOCKHOLDERS' EQUITY			
Current liabilities:			
Line of credit	\$ 2,580	\$ 2,460	
Accounts payable	4,261	3,717	
Deferred income taxes	472	326	
Obligations under capital leases	597	431	
Other current liabilities	6,106	6,513	
Total current liabilities	14,016	13,447	
Obligations under capital leases	1,124	1,403	
Deferred income taxes	708	488	
Other long-term liabilities	3,700	2,820	
Total liabilities	19,548	18,158	
Commitments, contingencies and subsequent events (Note 15)			

Edgar Filing: STAAR SURGICAL CO - Form 10-K

Stockholders' equity:

Common stock, \$0.01 par value; 60,000 shares authorized: 36,041 and 35,084 shares issued and outstanding at December 30, 2011 and December 31, 2010, respectively	361	351
Additional paid-in capital	157,382	152,014
Accumulated other comprehensive income	2,405	2,100
Accumulated deficit	(130,690)	(132,038)
Total stockholders' equity	29,458	22,427
Total liabilities and stockholders' equity	\$49,006	\$40,585

See accompanying summary of accounting policies and notes to consolidated financial statements.

F-4

STAAR SURGICAL COMPANY AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF OPERATIONS

Years Ended December 30, 2011, December 31, 2010, and January 1, 2010

	2011	2010	2009
	(In thousands, except per share amounts)		
Net sales	\$62,765	\$54,958	\$51,060
Cost of sales	20,396	19,882	19,737
Gross profit	42,369	35,076	31,323
Selling, general and administrative expenses:			
General and administrative	14,932	14,778	15,009
Marketing and selling	17,726	17,176	15,300
Research and development	5,868	5,724	5,893
Other general and administrative expenses	1,060	—	—
Operating income (loss)	2,783	(2,602)	(4,879)
Other income (expense):			
Interest income	32	43	67
Interest expense	(523)	(896)	(1,317)
Gain (loss) on foreign currency transactions	86	(87)	124
Loss on early extinguishment of note payable	—	(267)	—
Other income, net	326	128	257
Other expense, net	(79)	(1,079)	(869)
Income (loss) before provision for income taxes	2,704	(3,681)	(5,748)
Provision for income taxes	1,356	432	1,154
Income (loss) from continuing operations	1,348	(4,113)	(6,902)
Income from discontinued operations, net of income taxes	—	4,166	702
Net income (loss)	\$1,348	\$53	\$(6,200)
Income (loss) per share from continuing operations – basic	\$0.04	\$(0.12)	\$(0.21)
Income (loss) per share from continuing operations – diluted	\$0.04	\$(0.12)	\$(0.21)
Income per share from discontinued operations – basic and diluted	\$—	\$0.12	\$0.02
Net income (loss) per share – basic	\$0.04	\$(0.00)	\$(0.19)
Net income (loss) per share – diluted	\$0.04	\$(0.00)	\$(0.19)
Weighted average shares outstanding – basic	35,434	34,825	32,498
Weighted average shares outstanding – diluted	36,878	34,825	32,498

See accompanying summary of accounting policies and notes to consolidated financial statements.

F-5

STAAR SURGICAL COMPANY AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

AND COMPREHENSIVE INCOME (LOSS)

Years Ended December 30, 2011, December 31 2010, and January 1, 2010

	Common Stock Shares	Common Stock Par Value	Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Retained Earnings (Accumulated Deficit)	Total
Balance, at January 2, 2009	29,503	\$ 295	\$ 138,811	\$ 2,812	\$ (125,891)	\$ 16,027
Net loss	—	—	—	—	(6,200)	(6,200)
Foreign currency translation adjustment	—	—	—	578	—	578
Pension liability adjustment, net of tax	—	—	—	(136)	—	(136)
Total comprehensive loss						(5,758)
Common stock issued upon exercise of options	—	—	1	—	—	1
Net proceeds from public offering	4,555	46	8,456	—	—	8,502
Stock-based compensation	312	3	1,572	—	—	1,575
Stock issued in lieu of vacation	6	1	23	—	—	24
Preferred stock accretion	—	—	(16)	—	—	(16)
Warrants issued to Broadwood	—	—	290	—	—	290
Common stock issued as payment for services	247	2	422	—	—	424
Vested restricted stock grants	124	1	—	—	—	1
Balance, at January 1, 2010	34,747	348	149,559	3,254	(132,091)	21,070
Net income	—	—	—	—	53	53
Foreign currency translation adjustment	—	—	—	(1,154)	—	(1,154)
Total comprehensive loss						(1,101)
Common stock issued upon exercise of options	330	3	1,121	—	—	1,124
Stock-based compensation	—	—	1,333	—	—	1,333
Preferred stock accretion	—	—	1	—	—	1
Vested restricted stock grants	7	—	—	—	—	—
Balance, at December 31, 2010	35,084	351	152,014	2,100	(132,038)	22,427
Net income	—	—	—	—	1,348	1,348
Foreign currency translation adjustment	—	—	—	(247)	—	(247)
Pension liability adjustment, net of tax	—	—	—	552	—	552

Edgar Filing: STAAR SURGICAL CO - Form 10-K

Total comprehensive income							1,653
Common stock issued upon exercise of options	851	9	3,334	—	—		3,343
Stock-based compensation	—	—	2,035	—	—		2,035
Vested restricted stock grants	106	1	(1)	—	—		—
Balance, at December 30, 2011	36,041	\$ 361	\$ 157,382	\$ 2,405	\$ (130,690)		\$ 29,458

See accompanying summary of accounting policies and notes to consolidated financial statements.

F-6

STAAR SURGICAL COMPANY AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS

Years Ended December 30, 2011, December 31, 2010, and January 1, 2010

	2011	2010 (In thousands)	2009
Cash flows from operating activities:			
Net income (loss)	\$1,348	\$ 53	\$(6,200)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:			
Income from discontinued operations	—	(4,166)	(702)
Depreciation of property and equipment	1,469	1,590	1,973
Amortization of intangibles	797	816	1,402
Amortization of discount	—	236	379
Deferred income taxes	367	253	220
Loss on extinguishment of debt	—	267	—
Fair value adjustment of warrant	117	144	40
Change in net pension liability	257	318	232
Loss (gain) on disposal of property and equipment	13	(2)	98
Stock-based compensation expense	1,914	1,248	1,428
Other	(320)	93	148
Changes in working capital:			
Accounts receivable, net	(435)	(207)	(604)
Inventories	(85)	1,521	1,425
Prepays, deposits and other current assets	(145)	780	(116)
Accounts payable	480	(1,204)	595
Other current liabilities	(431)	(5,522)	(554)
Net cash provided by operating activities of discontinued operations	—	(635)	1,663
Net cash provided by (used in) operating activities	5,346	(4,417)	1,427
Cash flows from investing activities:			
Proceeds from sale of subsidiary, net of transaction costs	—	11,824	—
Acquisition of property and equipment	(962)	(320)	(553)
Proceeds from the sale of property and equipment	26	29	23
Net change in other assets	47	24	(10)
Purchase of short-term investments	—	(219)	(24)
Sale of short-term investments	—	87	198
Decrease (increase) in restricted cash, including reinvested interest	—	7,396	(7,396)
Net cash provided by (used in) investing activities of discontinued operations	—	(50)	149
Net cash (used in) provided by investing activities	(889)	18,771	(7,613)
Cash flows from financing activities:			
Repayment of notes payable	—	(5,000)	—
Borrowings under lines of credit	—	—	642

Edgar Filing: STAAR SURGICAL CO - Form 10-K

Repayment of lines of credit	—	—	(642)
Repayment of capital lease lines of credit	(575)	(796)	(1,011)
Proceeds from the exercise of stock options	3,343	1,124	1
Redemption of Series A preferred stock	—	(6,800)	—
Net proceeds from public and private sale of equity securities	—	—	8,502
Net cash used in financing activities of discontinued operations	—	(50)	(136)
Net cash provided by (used in) financing activities	2,768	(11,522)	7,356
Effect of exchange rate changes on cash and cash equivalents	(19)	214	168
Increase in cash and cash equivalents	7,206	3,046	1,338
Cash and cash equivalents, at beginning of year	9,376	6,330	4,992
Cash and cash equivalents, at end of year	\$16,582	\$ 9,376	\$6,330

See accompanying summary of accounting policies and notes to consolidated financial statements.

F-7

STAAR SURGICAL COMPANY AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Years Ended December 30, 2011 and December 31, 2010

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 incorporated in 1982 for the purpose of developing, producing, and marketing intraocular lenses (“IOLs”) and other products for minimally invasive ophthalmic surgery. Principal products are IOLs and ICLs. IOLs are prosthetic intraocular lenses used to restore vision that has been adversely affected by cataracts, and include the Company’s lines of silicone and Collamer IOLs and the Preloaded Injector (a silicone or acrylic IOL preloaded into a single-use disposable injector). ICLs, consisting of the Company’s Visian ICL and TICL, are intraocular lenses used to correct refractive conditions such as myopia (near-sightedness), hyperopia (far-sightedness) and astigmatism.

As of December 30, 2011, the Company’s significant subsidiaries consisted of:

· STAAR Surgical AG, a wholly owned subsidiary formed in Switzerland to develop, manufacture and distribute certain of the Company’s products worldwide including ICL.

· STAAR Japan, a wholly owned subsidiary that designs, manufactures and sells IOLs and injector systems which are sold as integrated preloaded injectors.

The Company operates as one operating segment, the ophthalmic surgical market, for financial reporting purposes (see Note 19).

Basis of Presentation

The accompanying consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. All significant intercompany balances and transactions have been eliminated in consolidation.

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. The fiscal 2011, 2010 and 2009 financial statements are based on a 52-week period.

Foreign Currency

The functional currency of the Company and its Japanese subsidiary is the local currency. The functional currency of the Company's Swiss subsidiary is the U.S. dollar. Assets and liabilities of foreign subsidiaries are translated at rates of exchange in effect at the close of the period. Sales and expenses are translated at the weighted average of exchange rates in effect during the period. The resulting translation gains and losses are deferred and are shown as a separate component of stockholders' equity as accumulated other comprehensive income (loss). During 2011, 2010, and 2009, the net foreign translation gains or (losses) were (\$247,000), (\$1,154,000), and \$578,000, respectively; and net foreign currency transaction gains or (losses), included in the consolidated statements of operations under other income (expense) were, \$86,000, (\$87,000), and \$124,000, respectively.

Revenue Recognition

The Company recognizes revenue when realized or realizable and earned, which is when the following criteria are met: persuasive evidence of an arrangement exists; delivery has occurred; the sale price is fixed and determinable; and collectability is reasonably assured. The Company records revenue from non-consignment product sales when title and risk of ownership has been transferred, which is typically at shipping point, except for the STAAR Japan subsidiary, which is typically recognized when the product is received by the customer. STAAR Japan does not have significant deferred revenues as of December 30, 2011 as delivery to the customer is generally made within the same or the next date of shipment. The Company presents sales tax it collects from its customers on a net basis (excluded from revenues).

STAAR SURGICAL COMPANY AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Years Ended December 30, 2011 and December 31, 2010

The Company's products are marketed to ophthalmic surgeons, hospitals, ambulatory surgery centers or vision centers, and distributors. IOLs may be offered to surgeons and hospitals on a consignment basis. The Company maintains title and risk of loss of consigned inventory and recognizes revenue for consignment inventory when the Company is notified that the IOL has been implanted.

ICLs are sold only to certified surgeons who have completed requisite training or for use in scheduled training surgeries. As a result, STAAR substantively reduces the risk that the revenue it recognizes on shipment of ICLs would need to be reversed because of a surgeon's failure to qualify for its use.

For all sales, the Company is considered the Principal in the transaction as the Company, among other factors, bears general inventory risk, credit risk, has latitude in establishing the sales price, and bears authorized sales returns inventory risk and therefore, sales and cost of sales are reported separately in the statement of operations instead of a single, net amount. Cost of sales includes cost of production, freight and distribution, royalties, and inventory provisions, net of any purchase discounts.

The Company generally permits returns of product if the product is returned within the time allowed by our return policies and records an allowance for estimated returns at the time revenue is recognized. The Company's allowance for estimated returns considers historical trends and experience, the impact of new product launches, the entry of a competitor, availability of timely and pertinent information and the various terms and arrangements offered, including sales with extended credit terms. Sales are reported net of estimated returns.

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

Use of Estimates

The consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America and, as such, include amounts based on informed estimates and judgments of management with consideration given to materiality. For example, estimates are used in determining valuation allowances for uncollectible trade receivables, obsolete and excess inventory, deferred income taxes, and tax reserves. Estimates are also used in the evaluation of asset impairment, in determining the useful life of depreciable and definite-lived intangible assets, and in the variables used to calculate stock-based compensation. Actual results could differ materially from those estimates.

Cash and Cash Equivalents

The Company considers all highly liquid investments purchased with a maturity of three months or less to be cash equivalents. The Company maintains cash deposits with major banks which from time to time may exceed federally insured limits. The Company periodically assesses the financial condition of the institutions and believes that the risk of any loss is minimal.

Restricted Cash and Short-Term Investments

On March 2, 2010, as part of the disposition of the Domilens subsidiary, the Company deposited 100,000 Euro (approximately \$133,000, based on the rate of exchange on December 30, 2011) into a restricted escrow account to be held against payment of any unaccrued taxes assessed for periods prior to December 31, 2009. Funds remaining on December 30, 2011, were to be returned to STAAR. During February 2012, the Company received the full amount of the deposit, including interest, which totaled \$134,000. The Company has classified this restricted cash as a current asset commensurate with the related contingent tax liability included in other current liabilities as of the Closing Date.

STAAR SURGICAL COMPANY AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Years Ended December 30, 2011 and December 31, 2010

Concentration of Credit Risk

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. One foreign customer accounted for approximately 19% of the Company's consolidated trade receivables balance as of December 30, 2011. The same customer accounts for approximately 13% and 11% of our consolidated net revenue as of December 30, 2011 and December 31, 2010, 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, in the aggregate, have not exceeded management's expectations.

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:

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 and 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.

Edgar Filing: STAAR SURGICAL CO - Form 10-K

Level 3 – Inputs to the valuation methodology are unobservable; that reflect management’s own assumptions about the assumptions market participants would make and significant to the fair value.

The carrying values reflected in the consolidated balance sheets for cash and cash equivalents, short-term investments, trade accounts receivable and accounts payable approximate their fair values because of the short maturity of these instruments.

Inventories, Net

Inventories, net are valued at the lower of cost, determined on a first-in, first-out basis, or market. Inventories include the costs of raw material, labor, and manufacturing overhead, work in process and finished goods. 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 lease term. Major improvements are capitalized and minor replacements, maintenance and repairs are charged to expense as incurred.

Depreciation is generally computed using the straight-line method over the estimated useful lives of the assets:

Machinery and equipment	5-10 years
Furniture and equipment	3-7 years
Computer and peripherals	2-5 years
Leasehold improvements	(a)

(a) Leasehold improvements are depreciated over the shorter of the useful life of the asset or the term of the associated leases.

Goodwill

STAAR SURGICAL COMPANY AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Years Ended December 30, 2011 and December 31, 2010

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. During the fourth quarter of fiscal 2011 and 2010, the Company performed its annual impairment test and determined that its goodwill was not impaired. As of December 30, 2011 and December 31, 2010, the carrying value of goodwill was \$1.8 million.

Long-Lived Assets

The Company reviews property 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. We measure 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 30, 2011 and no impairment was identified.

Amortization is computed on the straight-line basis over the estimated useful lives of the assets which range from 3 to 21 years for patents and licenses, 10 years for customer relationships, and 3 to 10 years for developed technology.

Research and Development Costs

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

Income Taxes

The Company recognizes deferred tax assets and liabilities for temporary differences between the financial reporting basis and the tax basis of the Company's assets and liabilities, net operating loss and credit carryforwards, and uncertainty in income taxes recognized in accordance with ASC 740-10 "Income Taxes". Valuation allowances, or reductions to deferred tax assets, are recognized if, based on the weight of available evidence, it is more likely than not that some portion or all of 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.

We recognize 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. We recognize accrued interest related to uncertain tax positions as a component of income tax expense, and penalties, if incurred, are recognized as a component of operating income.

Basic and Diluted Income (Loss) Per Share

The consolidated financial statements include "basic" and "diluted" per share information. Basic per share information is calculated by dividing net income (loss) by the weighted average number of shares outstanding. Diluted per share information is calculated by also considering the impact of potential common stock on both net income and the weighted number of shares outstanding.

Employee Defined Benefit Plans

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

STAAR SURGICAL COMPANY AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Years Ended December 30, 2011 and December 31, 2010

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

ASC 715-30 requires recognition of the funded status, or difference between the fair value of plan assets and the projected benefit obligations of the pension plan on the statement of financial position, with a corresponding adjustment to accumulated other comprehensive income. 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 statement of operations. The liabilities and annual income or expense of both plans are determined using methodologies that involve several actuarial assumptions, the most significant of which are the discount rate and the expected long-term rate of asset return (for Swiss Plan only) (based on the market-related value of assets). The fair values of plan assets are determined based on prevailing market prices (see Note 13).

Stock Based Compensation

Stock-based compensation expense for all stock-based compensation awards granted is based on the grant-date fair value estimated. 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 (see Note 14).

The Company also issues Restricted Stock, which are unvested shares issued at fair market value on the date of grant. They typically vest over a service period ranging between one and four years and are subject to forfeiture until vested or the service period is achieved, and the restriction is lapsed or terminated. The stock compensation expense is generally recognized by the Company as the stock vests, based on the fair value of the stock on the vesting date and the vested number of shares less any amounts paid for the stock, which is typically the par value of the shares.

The Company accounts for options granted to persons other than employees and directors under ASC 505-50. As such, the fair value of such options is periodically remeasured using the Black-Scholes option-pricing model and income or expense is recognized over the vesting period.

Accounting for Warrants

The Company accounts for the issuance of Company derivative equity instruments in accordance with ASC 815-40 “Derivatives and Hedging”. The Company has agreed to use its best efforts to register and maintain registration of the common shares underlying certain warrants (the “Warrant Shares”) that were issued by the Company with debt instruments, so that the warrant holder may freely sell the Warrant Shares if the warrant is exercised, and the Company agreed that in any event it would secure and maintain effective registration within four months of issuance. In addition, while the relevant warrant agreement does not require cash settlement if the Company fails to register and maintain registration of the Warrant Shares, it does not specifically preclude cash settlement. As a result ASC 815-40 requires the Company to assume that in the absence of continuous effective registration it may be required to settle these warrants for cash when they are exercised. Accordingly, the Company’s agreement to register and maintain registration of the Warrant Shares without express terms for settlement in the absence of continuous effective registration is presumed to create a liability to settle these warrants in cash, requiring liability classification. Included in other long-term liabilities with a fair value of \$362,000 and \$244,000 as of December 30, 2011 and December 31, 2010, respectively, are 70,000 warrants issued in March 2007 to Broadwood in connection with a loan which has since been repaid. The Company has issued other warrants (1.4 million) under an agreement that expressly provides that if the Company fails to satisfy continuous registration requirements the Company will be obligated only to issue additional common stock as the holder’s sole remedy, with no possibility of settlement in cash. The Company accounts for those warrants as equity because additional shares are the only form of settlement available to the holder. The Company uses the Black-Scholes option pricing model as the valuation model to estimate the fair value of all warrants. The Company evaluates the balance sheet classification of the warrants during each reporting period. Expected volatilities are based on historical volatility of the Company’s stock. The expected life of the warrant is determined by the amount of time remaining on the original six year term of the relevant warrant agreement. The risk-free rate of return for periods within the contractual life of the warrant is based on the U.S. Treasury yield curve in effect at each reporting period. Any gains or losses from period to period resulting from the changes in fair value of the warrants classified as a liability are included as an increase or decrease of other income (expense). The warrants that are accounted for as equity are only valued on the issuance date and not subsequently revalued.

STAAR SURGICAL COMPANY AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Years Ended December 30, 2011 and December 31, 2010

Comprehensive Income (Loss)

The Company presents comprehensive income (loss) in its Consolidated Statements of Stockholders' Equity and Comprehensive Income (Loss) in accordance with ASC 220-10 "Comprehensive Income". Total comprehensive loss includes, in addition to net income (loss), changes in equity that are excluded from the consolidated statements of operations and are recorded directly into a separate section of stockholders' equity on the consolidated balance sheets.

Recent Accounting Pronouncements

In June 2011, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update No. 2011-05, "Presentation of Comprehensive Income" (ASU 2011-05). Under ASU 2011-05, an entity has the option to present the total of comprehensive income, the components of net income, and the components of other comprehensive income either in a single continuous statement of comprehensive income or in two separate but consecutive statements. Under both options, an entity will be required to present each component of net income along with total net income, each component of other comprehensive income along with a total for other comprehensive income, and a total amount for comprehensive income. In December 2011, the FASB issued ASU 2011-12, "Deferral of the Effective Date for Amendments to the Presentation of Reclassifications of Items Out of Accumulated Other Comprehensive Income in Accounting Standards Update No. 2011-05" (ASU 2011-12), which deferred the requirement to present on the face of the financial statements reclassification adjustments for items that are reclassified from other comprehensive income to net income while the FASB further deliberates this aspect of the proposal. The amendments contained in ASU 2011-05 do not change the items that must be reported in other comprehensive income or when an item of other comprehensive income must be reclassified to net income. The amendments also do not affect how earnings per share is calculated or presented. ASU 2011-05, as amended by ASU 2011-12, is effective for the Company's fiscal year beginning on December 31, 2011. Although adopting the guidance will not impact the accounting for comprehensive income, it will affect the presentation of components of comprehensive income by eliminating the historical practice of showing these items within the consolidated statements of stockholders' equity.

In May 2011, the FASB issued ASU No. 2011-04, Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and IFRSs" (ASU 2011-04) to provide a consistent definition of fair value and

ensure that the fair value measurement and disclosure requirements are similar between GAAP and International Financial Reporting Standards. ASU 2011-04 changes certain fair value measurement principles and enhances the disclosure requirements, particularly for level 3 fair value measurements. ASU 2011-04 is effective for the Company's fiscal year beginning on December 31, 2011 and must be applied prospectively. The Company does not expect the adoption of ASU 2011-04 to have a material impact on the consolidated financial statements.

Prior Year Reclassifications

Certain reclassifications have been made to the prior financial statement information to conform to current presentation.

Note 2 — Acquisition of STAAR Japan

On December 29, 2007 (the "Closing Date"), during STAAR's 2008 fiscal year, STAAR acquired the remaining 50% of the shares of Canon Staar Co., Inc. ("Canon Staar") that had been owned previously by Canon Inc. and Canon Marketing Japan Inc. ("Canon Marketing" and, collectively with Canon Inc., the "Canon companies"). In the transaction (the "Acquisition"), STAAR obtained 100% ownership of Canon Staar, which was renamed STAAR Japan, Inc. ("STAAR Japan") as of the acquisition date.

In connection with the Acquisition, the material terms of the Joint Venture Agreement and other documents governing the joint venture were terminated. This included the termination of the pre-existing distribution arrangement of Canon Staar under which Canon Marketing had the exclusive right to distribute Canon Staar's products in Japan prior to the Acquisition.

STAAR SURGICAL COMPANY AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Years Ended December 30, 2011 and December 31, 2010

Note 3 – Disposal of Domilens Subsidiary

On March 2, 2010 (the “Closing Date”), STAAR Surgical Company completed the divestiture (the “Transaction”) of all of its interest in its German distribution subsidiary, Domilens GmbH (“Domilens”) through a management buyout led by funds managed by Hamburg-based Small Cap Buyout Specialist BPE Unternehmensbeteiligungen GmbH (“BPE”). To effectuate the Transactions “STAAR Surgical AG” (“STAAR AG”), STAAR’s Swiss subsidiary and holder of 100% of the shares of Domilens, signed a Stock Purchase agreement (the “Agreement”) with Domilens Akquisitionen GmbH (“Domilens Akquisitionen”) on February 24, 2010. Domilens Akquisitionen became a newly formed entity 74% owned by BPE and 26% owned by management of Domilens.

After deducting expenses of the sale totaling approximately \$1.2 million, including estimated taxes of \$46,000, the net cash proceeds from the transaction were approximately \$11.8 million.

The Transaction was accounted for as a divestiture as of the closing date, March 2, 2010, and Domilens was deconsolidated as of that date. The net gain on sale of Domilens was \$4.1 million, calculated and recorded as of the closing date, as the difference between the fair value of consideration received of approximately \$11.8 million in cash (net of taxes and direct transaction costs) and the \$7.7 million carrying value of Domilens’ net assets (assets, excluding cash which was offset as part of net proceeds received, less liabilities) pursuant to ASC 810-10-40. Included in the net assets disposed of was goodwill of approximately \$6.3 million resulting from the acquisition of Domilens by STAAR, which was completed in stages during a five-year period between 1998 and 2003.

The Company’s results of operations for the divested Domilens subsidiary have been reported as discontinued operations for all periods presented and, accordingly, all prior periods reported in the consolidated statements of operations and of cash flows have been adjusted to conform to this presentation. All sales made by STAAR after the closing date to unaffiliated Domilens GmbH, pursuant to the Distribution Agreement, have been included in STAAR’s continuing operations.

Note 4 — Accounts Receivable — Trade, Net

Accounts receivable – trade, net consisted of the following at December 30, 2011 and December 31, 2010 (in thousands):

	2011	2010
Domestic	\$1,456	\$1,405
Foreign	8,761	8,237
	10,217	9,642
Less allowance for doubtful accounts and sales returns	1,128	1,423
	\$9,089	\$8,219

Note 5 — Inventories, Net

Inventories, net consisted of the following at December 30, 2011 and December 31, 2010 (in thousands):

	2011	2010
Raw materials and purchased parts	\$1,883	\$1,920
Work in process	2,055	2,255
Finished goods	7,476	7,349
	11,414	11,524
Less inventory reserves	481	981
	\$10,933	\$10,543

STAAR SURGICAL COMPANY AND SUBSIDIARIES**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS****Years Ended December 30, 2011 and December 31, 2010****Note 6 — Prepaids, Deposits, and Other Current Assets**

Prepaids, deposits, and other current assets consisted of the following at December 30, 2011 and December 31, 2010 (in thousands):

	2011	2010
Prepaids and deposits	\$1,330	\$1,219
Other current assets	591	496
	\$1,921	\$1,715

Note 7 — Property, Plant and Equipment

Property, plant and equipment consisted of the following at December 30, 2011 and December 31, 2010 (in thousands):

	2011	2010
Machinery and equipment	\$13,654	\$13,069
Furniture and fixtures	4,324	3,841
Leasehold improvements	4,783	4,245
	22,761	21,155
Less accumulated depreciation	18,539	17,423
	\$4,222	\$3,732

Depreciation expense from continuing operations for the years ended December 30, 2011, December 31, 2010, and January 1, 2010 was approximately \$1.5 million, \$1.6 million, and \$2.0 million, respectively (adjusted for Domilens).

Note 8 – Intangible Assets, Net

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

	December 30, 2011			December 31, 2010		
	Gross Carrying Amount	Accumulated Amortization	Net	Gross Carrying Amount	Accumulated Amortization	Net
Amortized intangible assets:						
Patents and licenses	\$10,868	\$(9,508)) \$1,360	\$10,827	\$(9,064)) \$1,763
Customer relationships	2,023	(809)) 1,214	1,929	(579)) 1,350
Developed technology	1,286	(871)) 415	1,226	(667)) 559
Total	\$14,177	\$(11,188)) \$2,989	\$13,982	\$(10,310)) \$3,672

Aggregate amortization expense for amortized intangible assets was \$797,000, \$816,000, and \$1,402,000 for the years ended December 30, 2011, December 31, 2010, and January 1, 2010, respectively.

STAAR SURGICAL COMPANY AND SUBSIDIARIES**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS****Years Ended December 30, 2011 and December 31, 2010**

The following table shows estimated amortization expense for intangible assets for each of the next five succeeding years (in thousands):

Fiscal Year	Amount
2012	\$661
2013	507
2014	458
2015	326
2016	324
Thereafter	713
Total	\$2,989

Note 9 — Other Current Liabilities

Other current liabilities consisted of the following at December 30, 2011 and December 31, 2010 (in thousands):

	2011	2010
Accrued salaries and wages	\$2,051	\$2,121
Accrued bonuses	1,520	751
Accrued severance	—	570
Customer credit balances	559	566
Accrued insurance	392	422
Accrued audit expenses	322	417
Accrued income taxes	324	147
Other ⁽¹⁾	938	1,519
	\$6,106	\$6,513

⁽¹⁾No item in “Other” above exceeds 5% of total other current liabilities.

Note 10 — Notes Payable

Lines of Credit

The Company’s Japanese subsidiary, STAAR Japan, has an agreement, as amended on June 30, 2009, with Mizuho Bank which provides for borrowings of up to 300,000,000 Yen (approximately \$3.9 million based on the rate of exchange on December 30, 2011), at an interest rate equal to the Tokyo short-term prime interest rate (approximately 1.475% as of December 30, 2011) plus 1.125% and may be renewed annually (the current line expires on April 2, 2012). The credit facility is not collateralized. The Company had 200,000,000 Yen outstanding on the line of credit as of December 30, 2011 and December 31, 2010, (approximately \$2.6 million and \$2.5 million based on the foreign exchange rates on December 30, 2011 and December 31, 2010, respectively) which approximates fair value due to the short-term maturity and market interest rates of the line of credit. In case of default, the interest rate will be increased to 14% per annum. As of December 30, 2011, 100,000,000 Yen (approximately \$1.3 million, based on the rate of exchange on December 30, 2011) was available for borrowing.

In August 2010, the Company’s wholly-owned Swiss subsidiary, STAAR Surgical AG, entered into a credit agreement with Credit Suisse (the “Bank”). The credit agreement provides for borrowing of up to 1,000,000 CHF (Swiss Francs) \$1,060,000 at the rate of exchange on December 30, 2011), 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 credit agreement is automatically renewed on an annual basis based on the same terms assuming there is no default. The credit agreement may be terminated by either party at any time in accordance with its general terms and conditions. The credit facility 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 credit 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 AG’s independent auditors’ report. There were no borrowings outstanding as of December 30, 2011 and the full amount of the line was available for borrowing.

STAAR SURGICAL COMPANY AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Years Ended December 30, 2011 and December 31, 2010

Covenant Compliance

The Company is in compliance with covenants of its credit facilities and lines of credit as of December 30, 2011.

Broadwood Promissory Note

The Company had a \$5 million principal amount of indebtedness under an Amended and Restated Senior Secured Promissory Note (the "Note") held by Broadwood Partners, L.P. ("Broadwood"), which was issued on April 13, 2009 and was scheduled to mature on December 14, 2010.

On June 22, 2010, the Company repaid the \$5 million principal plus \$322,000 in accrued interest. As a result of repaying the Note, the Company recorded a \$267,000 loss on early extinguishment due to the write-off of the remaining unamortized debt discount and issuance costs on the date of the repayment; this loss is included in Other income (expense), net, in the accompanying consolidated statements of operations.

As additional consideration for the loan, on December 14, 2007, the Company also entered into a Warrant Agreement with Broadwood (the "December 2007 Warrant Agreement") granting the right to purchase up to 700,000 shares of Common Stock at an exercise price of \$4.00 per share, exercisable for a period of six years. The December 2007 warrant has been accounted for as an equity instrument.

The December 2007 Note also provided that if any indebtedness remained outstanding under the Note on June 1, 2009, the Company would issue additional warrants on the same terms as set forth in the December 2007 Warrant Agreement in a number equal to 700,000 times the percentage of the original \$5 million principal that remains outstanding. On June 1, 2009, as the Note remained outstanding, the Company issued an additional 700,000 warrants to Broadwood, which were valued at approximately \$290,000 and included as debt discount and additional paid-in

capital in the consolidated balance sheet upon issuance. The December 2007 Warrant Agreement provides that the Company will register the shares issuable upon exercise of the warrants with the Securities Exchange Commission. The Company filed and secured effectiveness of a registration statement covering resale of the shares. If the Company fails to keep the registration statement effective and the lapse exceeds permitted suspensions, as the holder's sole remedy, the Company will be obligated to issue an additional 30,000 warrants for each month that the Company does not meet this effectiveness requirement through the term of the warrants ("Penalty Warrants") (a maximum of approximately 1,230,000 warrants issuable as of December 30, 2011 under an assumed noncompliance as of that date). The Company does not consider the issuance of Penalty Warrants likely.

The fair value of the warrants was treated as an additional discount on the loan and was being amortized using the effective interest method over the life of the loan (which approximates an effective interest rate of 32% per annum, assuming the 20% cash interest rate is maintained throughout the life of the Note). During the years ended December 31, 2010 and January 1, 2010, approximately \$236,000 and \$379,000 of the discount was amortized and included in interest expense.

The fair value of the warrants was estimated on June 1, 2009 issuance dates using a Black-Scholes option valuation model applying the assumptions noted in the following table:

	As of
	June 1, 2009
Common stock price per share	\$ 1.01
Number of warrants	700,000
Expected dividends	0 %
Expected volatility	74.4 %
Risk-free rate	3.28 %
Life (in years)	6.0

STAAR SURGICAL COMPANY AND SUBSIDIARIES**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS****Years Ended December 30, 2011 and December 31, 2010**

Broadwood also holds warrants to purchase 70,000 shares of Common Stock at an exercise price of \$6.00 per share, which was issued in connection with a loan of \$4 million by Broadwood under a Promissory Note dated March 21, 2007. The March 21, 2007 Promissory Note was repaid in full on June 2007. As explained in Note 1, these warrants were classified as a liability. As of December 30, 2011 and December 31, 2010, the fair value was \$362,000 and \$244,000, and the \$118,000 change in fair value since December 31, 2010 has been recorded in other expense.

The fair value of the warrant that was classified as a liability on December 30, 2011 and December 31, 2010 were based on Black-Scholes option valuation model applying the assumption noted on the following table below:

	December 30, 2011		December 31, 2010	
Common stock price per share	\$ 10.49		\$ 6.10	
Number of warrants	70,000		70,000	
Expected dividends	0	%	0	%
Expected volatility	63.61	%	103.86	%
Risk-free rate	.25	%	1.02	%
Life (in years)	1.25		2.25	

Note 11 — Series A Redeemable, Convertible Preferred Stock

Under its Certificate of Incorporation, the Company has 10,000,000 shares of “blank check” preferred stock, which the Board of Directors is authorized to issue with such rights, preferences and privileges as the Board may determine. On October 22, 2007, the Board approved the designation of 1,700,000 shares of the preferred stock as Series A Redeemable Convertible Preferred Stock (“Preferred Stock”) to be issued in connection with the acquisition of the 50% interest in Canon Staar Co., Inc. which was consummated on December 29, 2007. On December 29, 2007, the Company issued the 1,700,000 shares of Preferred Stock to the Canon companies as partial consideration for their shares of Canon Staar Co., Inc. at an estimated fair value of \$4.00 per share, or \$6.8 million in the aggregate.

The Preferred Stock was convertible into shares of the Company's common stock at any time after the issuance date at a one-to-one conversion ratio that was adjustable only for stock splits, combinations, subdivisions, dividends or recapitalizations ("Conversion Ratio"). On the fifth anniversary of the issuance date, the Preferred Stock would expire and each share of Preferred Stock would automatically convert to common stock of the Company at the Conversion Ratio.

The Preferred Stock was redeemable by the Company at any time on or after the first anniversary of the issuance date at a price of \$4.00 per share plus any accrued or declared but unpaid dividends ("Redemption Price"). The holders of the Preferred Stock had a right, exercisable at any time on or after the third anniversary (December 29, 2010) of the issuance date by a majority vote of the Preferred Stock holders with at least 30 days' written notice, to require the Company to redeem the Preferred Stock at the Redemption Price.

On April 23, 2010, STAAR issued a call notice to the holders of its 1,700,000 outstanding shares of Preferred Stock establishing May 24, 2010 as the redemption date for the Preferred Stock. On the redemption date each share of preferred stock could be redeemed for \$4.00 per share unless it had previously been converted to the Company's common stock. The holders of the preferred stock could convert their shares of Preferred Stock into common stock at the one-to-one ratio at any time until the close of business on May 17, 2010. On May 24, 2010, the Company redeemed all outstanding shares of preferred stock in cash for \$4.00 per share, or \$6.8 million in aggregate. There are no Preferred Shares outstanding since the redemption.

STAAR SURGICAL COMPANY AND SUBSIDIARIES**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS****Years Ended December 30, 2011 and December 31, 2010****Note 12 — Income Taxes**

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

	2011	2010	2009 ⁽¹⁾
Current tax provision:			
U.S. federal	\$—	\$—	\$—
State	13	13	15
Foreign	1,012	602	1,341
Total current provision	1,025	615	1,356
Deferred tax provision:			
U.S. federal and state	—	—	—
Foreign	331	(183)	(202)
Total deferred provision	331	(183)	(202)
Provision for income taxes	\$1,356	\$432	\$1,154

⁽¹⁾Adjusted to reflect effects of discontinued operations.

As of December 30, 2011, the Company had \$121.1 million of U.S. federal net operating loss carryforwards available to reduce future income taxes. The net operating loss carryforwards expire in varying amounts between 2020 and 2031.

The Company had accrued income taxes receivable of \$10,000 and \$151,000 at December 30, 2011 and December 31, respectively, primarily due to taxes payable in foreign jurisdictions.

Edgar Filing: STAAR SURGICAL CO - Form 10-K

The provision for income before taxes differs from the amount computed by applying the statutory federal income tax rate to income before taxes as follows (amounts in thousands):

	2011		2010		2009 ⁽¹⁾	
Computed provision for taxes based on income at statutory rate	34.0 %	\$919	34.0 %	\$(1,252)	34.0 %	\$(1,954)
Increase (decrease) in taxes resulting from:						
Permanent differences	1.4	37	(0.9)	33	(0.5)	23
State minimum taxes, net of federal income tax benefit	0.3	9	(0.2)	9	(0.2)	10
State tax benefit	(4.3)	(116)	5.6	(207)	13.7	(786)
Tax rate difference due to foreign statutory rate	(19.7)	(529)	5.7	(208)	2.9	(164)
Foreign tax benefit	11.6	312	3.7	(137)	4.7	(273)
Foreign earnings not permanently reinvested	29.1	788	—	—	(17.4)	1,001
Foreign dividend withholding	5.5	147	(12.0)	440	(3.1)	179
Return to provision adjustment	—	—	—	—	—	—
FAS 123R	—	—	(23.7)	873	—	—
Other	1.4	37	0.2	(7)	(0.4)	25
Valuation allowance	(9.2)	(248)	(24.1)	888	(53.8)	3,093
Effective tax provision rate	50.1 %	\$1,356	(11.7)%	\$432	(20.1)%	1,154

⁽¹⁾Adjusted to reflect effects of discontinued operations.

STAAR SURGICAL COMPANY AND SUBSIDIARIES**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS****Years Ended December 30, 2011 and December 31, 2010**

Included in the state tax provision is an increase to the state deferred tax asset and corresponding increase to the valuation allowance of \$118,000, \$207,000, and \$786,000, for 2011, 2010 and 2009 respectively. This results in a total state tax provision of \$13,000 for 2011, \$13,000 for 2010, and \$15,000 for 2009.

For 2011, included in the foreign tax provision is a decrease to the foreign deferred tax asset and corresponding decrease to the valuation allowance of \$312,000. For 2010 and 2009, there was an increase to the foreign deferred tax asset and corresponding increase to the valuation allowance of \$137,000 and \$273,000, respectively. This results in a foreign tax provision of \$1,343,000 for 2011, \$419,000 for 2010, and \$1,139,000 for 2009.

All earnings from the company's subsidiaries are not considered to be permanently reinvested. Accordingly, the Company provides withholding and U.S. taxes on all unremitted foreign earnings. During 2011 and 2010 the Company paid \$0 and \$435,000 respectively, in withholding taxes to the Swiss government due to the repatriation of approximately \$0 in 2011 and \$8.7 million in 2010 of earnings from its Swiss subsidiary, STAAR Surgical AG.

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) as of December 30, 2011 and December 31, 2010 are as follows (in thousands):

	2011	2010
Current deferred tax assets (liabilities):		
Allowance for doubtful accounts and sales returns	\$90	\$245
Inventories	270	421
Accrued vacation	490	434
Other	(110)	(123)
State taxes	3	3
Accrued legal judgment and other accrued expenses	211	152

Edgar Filing: STAAR SURGICAL CO - Form 10-K

Valuation allowance	(1,426)	(1,458)
Total current deferred tax liabilities	\$(472)	\$(326)
Non-current deferred tax assets (liabilities):		
Net operating loss carryforwards	51,334	51,077
Stock-based payments	1,311	1,128
Business, foreign and AMT credit carryforwards	788	723
Capitalized R&D	597	602
Contributions	160	190
Pensions	812	713
Depreciation and amortization	54	100
Foreign tax withholding	(711)	(869)
Foreign earnings not permanently reinvested	(4,789)	(3,780)
Other	33	61
Valuation allowance	(50,145)	(50,231)
Total non-current deferred tax liabilities	\$(556)	\$(286)

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 realized. Cumulative losses weigh heavily in the assessment of the need for a valuation allowance. Due to the Company's history of losses in the U.S., the valuation allowance fully offsets the value of U.S. deferred tax assets on the Company's balance sheet as of December 30, 2011. Further, under Federal Tax Law Internal Revenue Code Section 382, significant changes in ownership may restrict the future utilization of these tax loss carry forwards.

Included in deferred tax assets and liabilities are net non-current deferred tax assets of \$152,000 and \$202,000 for 2011 and 2010 respectively for Staar AG. Due to Staar AG's history of profits, the deferred tax assets are considered fully realizable.

STAAR SURGICAL COMPANY AND SUBSIDIARIES**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS****Years Ended December 30, 2011 and December 31, 2010**

The Company does not have any uncertain tax positions. The Company classifies any interest and penalties related to income taxes assessed by jurisdiction as part of income tax expense. The Company did not incur significant interest and penalties during 2011

The following tax years remain subject to examination:

Significant Jurisdictions	Open Years
U.S. Federal	2008 – 2010
California	2007 – 2010
Germany	2008 – 2010
Switzerland	2010
Japan	2007 – 2010

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

	2011	2010	2009
Domestic	\$(2,145)	\$(4,732)	\$(9,052)
Foreign	4,849	1,051	3,304
	\$2,704	\$(3,681)	\$(5,748)

Note 13 – Employee Benefit Plans

The Company maintains a passive pension plan (the “Swiss Plan”) covering employees of its Swiss subsidiary, which is accounted for as a defined benefit plan under the provisions of ASC 715-30, “Defined Benefit Plans – Pension”.

Defined Benefit Plan-Switzerland

In Switzerland employers are required to provide a minimum pension plan for their staff. The Swiss Plan is financed by contributions of both the employees and employer. 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 funded status of the Swiss benefit plan at December 30, 2011 and December 31, 2010 is as follows:

	2011	2010
Change in Projected Benefit Obligation:		
Projected benefit obligation, beginning of period	\$4,868	\$3,836
Service cost	414	328
Interest cost	127	120
Participant contributions	275	248
Benefits paid	(641)	(489)
Actuarial (gain) loss on obligation	(333)	825
Projected benefit obligation, end of period	\$4,710	\$4,868
Changes in Plan Assets:		
Plan assets at fair value, beginning of period	\$3,074	\$2,722
Actual return on plan assets (including foreign currency impact)	75	345
Employer contributions	275	248
Participant contributions	275	248
Benefits paid	(641)	(489)
Plan assets at fair value, end of period	\$3,058	\$3,074
Net Amount Recognized in Consolidated Balance Sheets:		
Underfunded, end of year	\$(1,652)	\$(1,794)
Other long term liabilities	\$(1,652)	\$(1,794)
Amount Recognized in Accumulated Other Comprehensive Loss, Net of Tax:		
Actuarial loss on plan assets	\$(610)	\$(589)
Actuarial loss on benefit obligation	(364)	(624)
Actuarial gain recognized in current year	163	88
Accumulated other comprehensive loss	\$(811)	\$(1,125)
Accumulated benefit obligation at end of year	\$(4,087)	\$(4,271)

STAAR SURGICAL COMPANY AND SUBSIDIARIES**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS****Years Ended December 30, 2011 and December 31, 2010**

The underfunded balance of \$1,652,000 and \$1,794,000 was included in other long-term liabilities on the consolidated balance sheets as of December 30, 2011 and December 31, 2010, respectively.

Net periodic pension cost associated with the Swiss Plan in the years ended December 30, 2011, December 31, 2010, and January 1, 2010 include the following components (in thousands):

	2011	2010	2009
Service Cost	\$414	\$328	\$307
Interest Cost	127	120	108
Expected return on plan assets	(101)	(91)	(91)
Actuarial loss recognized in current year	97	55	33
Net periodic pension cost	\$537	\$412	\$357

Changes in other comprehensive loss (net of tax) associated with the Swiss Plan in the year ended December 30, 2011 and December 31, 2010 include the following components (in thousands):

	2011	2010
Actuarial loss of current year	\$(238)	\$(446)
Actuarial (loss) income recorded in current year	(75)	43
Change in other comprehensive loss	\$(313)	\$(403)

The amount in accumulated other comprehensive loss as of December 30, 2011 that is expected to be recognized as a component of the net periodic pension costs in the subsequent year is \$54,000.

Net periodic pension cost and projected and accumulated pension obligation for the Company's Swiss Plan were calculated on December 30, 2011 and December 31, 2010 using the following assumptions:

Edgar Filing: STAAR SURGICAL CO - Form 10-K

	2011	2010
Discount rate	2.50 %	2.60 %
Salary increases	3.00 %	3.00 %
Expected return on plan assets	3.35 %	3.35 %
Expected average remaining working lives in years	10.60	9.90

The discount rates of 2.50% and 2.60% for the period ending December 30, 2011 and December 31, 2010, respectively are based on an assumed pension benefit maturity of 10 to 15 years. The rate was estimated using the rate of return for high quality Swiss corporate bonds that mature in eight years. This maturity was used as there are significant numbers of high quality Swiss bonds, but very few bonds issued with maturities with longer lives. As of December 30, 2011 and December 31, 2010, the average rate for high quality Swiss corporate bonds was 2.5% and 2.61% respectively. In order to determine an appropriate discount rate, the eight year rate of return was then extrapolated along the yield curve of Swiss government bonds.

F-22

STAAR SURGICAL COMPANY AND SUBSIDIARIES**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS****Years Ended December 30, 2011 and December 31, 2010**

The salary increase rate of 3% 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.

Plan assets categories in the Swiss Plan are comprised of the following (in thousands):

	2011	2010
Bonds and loans	\$2,186	\$2,090
Real estate (including real estate funds)	765	830
Equity securities	73	92
Liquid assets	34	62
	\$3,058	\$3,074

In accordance with ASC 820-10-35 the assets above are measured at fair value and are categorized into three different class levels. Level 1 assets are those whose value is based on quoted prices in active markets. Level 2 assets are those whose values are based on direct or indirect observable markets for similar assets. Level 3 assets are those whose values are unobservable. As of December 30, 2011, Level 1 assets in the Swiss Plan include bonds (65%), equity (2%) and liquid assets (1%). Level 2 assets are comprised of mortgages (14%), real estate assets (11%) and loans (7%). As of December 31, 2010, Level 1 assets in the Swiss Plan include bonds (60%), equity (3%) and liquid assets (2%). Level 2 assets are comprised of mortgages (13%), real estate assets (14%) and loans (8%).

The Company has contracted with the Allianz Suisse Life Insurance Company's BVG Collective Foundation to manage the Swiss Plan. The investment strategy is determined by the Swiss insurance company and applies to all members of the collective foundation.

In fiscal 2012, the Company expects to make cash contributions totaling approximately \$272,000 to the Swiss Plan.

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

Fiscal Year	
2012	\$46
2013	53
2014	61
2015	69
2016	78
2017 – 2020	623
Total	\$930

Defined Benefit Plan-Japan

In connection with the Company’s acquisition of the remaining interest in STAAR Japan, Inc., STAAR assumed the net pension liability under STAAR Japan’s noncontributory defined benefit pension plan (“Japan Plan”) substantially covering all of the employees of STAAR Japan. STAAR Japan accounts for the Japan Plan under the requirements of ASC 715-30. 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.

F-23

STAAR SURGICAL COMPANY AND SUBSIDIARIES**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS****Years Ended December 30, 2011 and December 31, 2010**

Effective September 30, 2009 (the “Distribution Date”), STAAR Japan management and the participants of the Japan Plan approved the distribution of the pension plan assets to its participants (the “Distribution”). All other terms and provisions of the Japan Plan remained unchanged except as described below. Prior to the Distribution Date, the plan assets were being held, invested and administered by Dai-ichi Mutual Life Insurance Company, the plan Custodian, and as of the Distribution Date, all the risks associated with the plan assets and its distribution to the participants of the plan were irrevocably accepted by and legally transferred to the Custodian. The Company accounted for this distribution as a partial settlement on the Distribution Date in accordance with ASC 715-30-35, *Defined Benefit Plans – Pension*. On September 30, 2009, the fair value of the Japan Plan assets were approximately 58 million Yen (approximately \$643,000 at the exchange rate in effect on that date), which were distributed to the participants based on their pro rata vested balances in October 2009. The Company recorded in earnings a \$26,000 gain on partial settlement of the Japan Plan calculated on a pro rata portion of the amount equal to the percentage reduction in the projected benefit obligation by the distribution amount.

Beginning October 1, 2009, STAAR Japan maintains and administers the plan (the “Amended Plan”) and funds the obligations of the Amended Plan from STAAR Japan’s operations. STAAR Japan is not required, and does not intend to provide any future contributions to the Amended Plan to meet benefit obligations and will therefore not have any plan assets. Benefit payments are made to beneficiaries from operating cash flows as they become due. The Amended Plan will retain all other provisions of the Japan Plan that existed prior to the distribution, except for two amendments made to the Amended Plan. First, since the Distribution was a taxable event to the participants, STAAR Japan agreed to increase future pension benefits to the participants to reimburse them for any additional taxes due from the Distribution when those benefits are paid. Second, the Amended Plan changed the benefit payment method to a lump-sum distribution only, whereas the Japan Plan prior to the amendment provided a choice of distribution of benefits either in lump-sum or an annuity.

The funded status of the benefit plan at December 30, 2011 and December 31, 2010 is as follows:

	2011	2010
Change in Projected Benefit Obligation:		
Projected benefit obligation, beginning of period	\$782	\$920
Service cost	174	234
Interest cost	6	12
Actuarial loss or (gain)	137	(413)

Edgar Filing: STAAR SURGICAL CO - Form 10-K

Benefits paid	(38)	(79)
Foreign exchange adjustment	47	108
Projected benefit obligation, end of period	\$1,108	\$782
Changes in Plan Assets:		
Plan assets at fair value, beginning of period	\$—	\$—
Actual return on plan assets	—	—
Employer contributions	—	—
Benefits paid	—	—
Distribution of plan assets	—	—
Foreign exchange adjustment	—	—
Plan assets at fair value, end of period	\$—	\$—
Net Amount Recognized in Consolidated Balance Sheets:		
Underfunded, end of period	\$(1,108)	\$(782)
Other long term liabilities	\$(1,108)	\$(782)
Amount Recognized in Accumulated Other Comprehensive Income:		
Transition obligation	\$101	\$85
Actuarial gain	207	461
Prior Service Cost	29	30
Accumulated other comprehensive income	\$337	\$576
Accumulated benefit obligation at end of year	\$(912)	\$(653)

STAAR SURGICAL COMPANY AND SUBSIDIARIES**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS****Years Ended December 30, 2011 and December 31, 2010**

The underfunded balance of \$1,108,000 and \$782,000 was included in other long-term liabilities on the consolidated balance sheets as of December 30, 2011 and December 31, 2010.

Net periodic pension cost associated with the Japan Plan for the years ended December 30, 2011 and December 31, 2010 include the following components (in thousands):

	2011	2010
Service cost	\$174	\$234
Interest cost	6	13
Net amortization of transition obligation	16	15
Actuarial Loss	(117)	(24)
Prior Service Cost	(1)	(1)
Net periodic pension cost	\$78	\$237

Changes in other comprehensive income (loss) associated with the Japan Plan for the years ended December 30, 2011 and December 31, 2010 include the following components (in thousands):

	2011	2010
Amortization of transitional obligation	\$16	\$15
Net actuarial (loss) gain of current year	(137)	413
Actuarial loss recorded in current year	(117)	(24)
Prior Service Cost	(1)	(1)
Change in other comprehensive income (loss)	\$(239)	\$403

The amount in accumulated other comprehensive income as of December 30, 2011 that is expected to be recognized as a component of the net periodic pension cost in fiscal 2012 is approximately \$45,000.

Edgar Filing: STAAR SURGICAL CO - Form 10-K

Net periodic pension cost and projected and accumulated pension obligation for the Company's Japan Plan were calculated on December 30, 2011 and December 31, 2010 using the following assumptions:

	2011	2010
Discount rate	.70 %	.70 %
Salary increases	2.00%	2.00%
Expected return on plan assets	N/A	N/A
Expected average remaining working lives in years	8.61	6.49

The discount rate of 0.7% for the periods ending December 30, 2011 and December 31, 2010 is based on the approximate Japanese government bond rate with a term of 10 to 20 years.

The salary increase average rate of 2% was based on the Company's best estimate of future increases over time.

On September 30, 2009, all assets of the Japan Plan were liquidated as part of the Distribution. The estimated future benefit payments for the Japan Plan are as follows (in thousands):

F-25

STAAR SURGICAL COMPANY AND SUBSIDIARIES**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS****Years Ended December 30, 2011 and December 31, 2010**

Fiscal Year	
2012	\$64
2013	70
2014	72
2015	86
2016	105
2017 – 2021	644
Total	\$1,041

Defined Contribution Plan

The Company maintains a 401(k) profit sharing plan (“401(k) Plan”) for the benefit of qualified employees in North America. During the fiscal year ended December 30, 2011, employees who participate may elect to make salary deferral contributions to the 401(k) Plan up to the \$16,500 of the employees’ eligible payroll subject to annual Internal Revenue Code maximum limitations. The Company makes a contribution of 50% of the employee’s contribution up to the first 2% of the employee’s compensation, and 25% of the next 4% of compensation. In addition, STAAR may make a discretionary contribution to qualified employees, in accordance with the 401(k) Plan. During the years ended December 30, 2011, December 31, 2010, and January 1, 2010, the Company made contributions, net of forfeitures, of \$150,000, \$123,000, and \$94,000, respectively, to the 401(k) Plan. The Company also made a one-time discretionary contribution of \$47,000 to qualified employees.

Note 14 — Stockholders’ Equity***Common Stock***

During fiscal year 2011, the Company issued 155,000 shares of restricted stock to certain employees. Restricted shares are issued at fair market value on the date of grant, vest over a period of one to four years, and are subject to forfeiture until vested or the service period is achieved and the restriction is lapsed or terminated. As the restriction

lapses and the stock vests, the expense is included in stock-based compensation. As of December 30, 2011 none of these restricted shares had vested.

Share-Based Payments

The Company issues new shares upon option exercise once the optionee remits payment for the exercise price. The compensation cost that has been charged against income is set forth below (in thousands):

	Fiscal Year Ended		
	December 30, 2011	December 31, 2010	January 1, 2010
Stock based compensation expense	\$ 1,361	\$ 852	\$ 926
Restricted stock expense	466	285	194
Common stock issued to employees	—	—	286
Consultant compensation	87	111	22
Total	\$ 1,914	\$ 1,248	\$ 1,428

There was no net income tax benefit recognized in the consolidated statements of operations for share-based compensation arrangements as the Company fully offsets net deferred tax assets with a valuation allowance (see Note 12). In addition, the Company capitalized \$121,000, \$85,000, and \$118,000 of stock based compensation to inventory for the fiscal years ended December 30, 2011, December 31, 2010, and January 1, 2010, respectively, and recognizes those amounts as expense in Cost of Sales as the inventory is sold.

Stock Option Plans

In fiscal year 2003, the Board of Directors approved the 2003 Omnibus Equity Incentive Plan (the “2003 Plan”) authorizing awards of equity compensation, including options to purchase common stock and restricted shares of common stock. The 2003 Plan amends, restates and replaces the 1991 Stock Option Plan, the 1995 Consultant Stock Plan, the 1996 Non-Qualified Stock Plan and the 1998 Stock Option Plan (the “Restated Plans”). Under provisions of the 2003 Plan, all of the unissued shares in the Restated Plans are reserved for issuance in the 2003 Plan. Each year the number of shares reserved for issuance under the 2003 Plan has been increased as necessary to provide that 2% of the total shares of common stock outstanding on the immediately preceding December 31 would be reserved for issuance, up to a maximum of 1,586,371 additional shares, and a maximum total of 6,500,000 shares issuable under the 2003 Plan and all of the Restated Plans incorporated in it. The 6,500,000 maximum shares were reached on January 1, 2007. On May 19, 2010, the stockholders of STAAR approved the Restated 2003 Omnibus Plan, which increased the number of shares available for grants under the Plan by 2,000,000 shares and extended the term of the plan to May 18, 2020.

Shares subject to grants under the 2003 Omnibus Plan and Restated Plans that lapse or terminate in accordance with their terms become available for new grants under the 2003 Omnibus Plan. As of December 30, 2011, approximately 1,712,198 shares were authorized and available for grants under the 2003 Omnibus Plan. The 2003 Plan provides for various forms of stock-based incentives. To date, of the available forms of awards under the 2003 Plan, the Company has granted only stock options and restricted stock. Options under the plan are granted at fair market value on the date of grant, become exercisable generally over a three- or four-year service 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 (as defined in the 2003 Plan). Restricted stock grants under the 2003 Plan generally vest over a period of one, three or four years. Pursuant to the plan, options for 3,058,778 shares were outstanding at December 30, 2011 with exercise prices ranging between \$0.95 and \$10.77 per share. There were 155,000 shares of restricted stock outstanding at December 30, 2011.

In fiscal year 1998, the Board of Directors approved the 1998 Stock Option Plan, authorizing the granting of options to purchase common stock or awards of common stock. Pursuant to the plan, options for 5,000 shares were outstanding at December 30, 2011 with an exercise price of \$3.60 per share. No further awards may be made under this plan.

During the fiscal year ended December 30, 2011, officers, employees and others exercised 850,958 options from the 1995, 1998, and 2003 stock option plans at prices ranging from \$0.95 to \$7.86 resulting in net cash proceeds to the Company totaling \$3,343,000.

Assumptions

The fair value of each option award is estimated on the date of grant using a Black-Scholes option valuation model applying the assumptions noted in the following table. Expected volatilities are based on historical volatility of the Company's stock. The Company uses historical data to estimate option exercise and employee termination behavior. The expected term of options granted is derived from the historical exercise activity over the past 15 years, and represents the period of time that options granted are expected to be outstanding. The Company has calculated a 10.05% estimated forfeiture rate used in the model for fiscal year 2011 option grants based on historical forfeiture experience. The risk-free rate for periods within the contractual life of the option is based on the U.S. Treasury yield curve in effect at the time of grant.

	Fiscal Year Ended					
	December 30, 2011		December 31, 2010		January 1, 2010	
Expected dividend yield	0	%	0	%	0	%
Expected volatility	77	%	80	%	74	%
Risk-free interest rate	1.82	%	2.13	%	1.92	%
Expected term (in years)	5.49		5.60		5.5	

F-27

STAAR SURGICAL COMPANY AND SUBSIDIARIES**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS****Years Ended December 30, 2011 and December 31, 2010**

A summary of option activity under the Plans as of December 30, 2011 is presented below:

	Shares	Weighted- Average Exercise Price	Weighted- Average Remaining Contractual Term	Aggregate Intrinsic Value (000's)
Options	(000's)			
Outstanding at December 31, 2010	3,331	4.35		
Granted	695	5.91		
Exercised	(851)	3.93		
Forfeited or expired	(111)	5.21		
Outstanding at December 30, 2011	3,064	\$ 4.79	6.51	\$ 17,369
Exercisable at December 30, 2011	1,979	\$ 4.48	5.14	11,894

The weighted-average grant-date fair value of options granted during the fiscal years ended December 30, 2011, December 31, 2010, and January 1, 2010, was \$3.85, \$3.13, and \$0.96 per option respectively. The total fair value of options vested during fiscal years ended December 30, 2011, December 31, 2010, and January 1, 2010, was \$1,049,000, \$1,143,000, and \$1,194,000, respectively. The total intrinsic value of options exercised during the fiscal years ended December 30, 2011, December 31, 2010, and January 1, 2010, was \$2,533,000, \$701,000, and \$1,000, respectively.

A summary of the Company's non-vested options as of December 30, 2011 and changes during the period is presented below:

	Options	Weighted- Average Grant Date Fair Value
	(000's)	
Nonvested Options		
Nonvested at December 31, 2010	885	\$ 2.89

Edgar Filing: STAAR SURGICAL CO - Form 10-K

G	Granted	694	4.16
V	Vested	(383)	2.70
F	Forfeited	(111)	3.78
N	Nonvested at December 30, 2011	1,085	\$ 5.35

As of December 30, 2011, there was \$2.5 million of total unrecognized compensation cost related to non-vested share-based compensation arrangements granted under the Plans. That cost is expected to be recognized over a weighted-average period of 2.00 years.

The following table summarizes information about stock options outstanding and exercisable at December 30, 2011 (in thousands, except per share data):

Range of Exercise Prices	Options				
	Number Outstanding at December 30, 2011	Weighted-Average Remaining Contractual Life	Weighted-Average Exercise Price	Number Exercisable at December 30, 2011	Weighted-Average Exercise Price
	\$0.95	60	7.25 years	\$ 0.95	39
\$1.56 to \$ 2.30	394	6.29 years	\$ 2.21	394	\$ 2.21
\$2.45 to \$ 3.60	312	7.24 years	\$ 3.23	181	\$ 3.10
\$3.75 to \$5.29	815	5.31 years	\$ 4.30	680	\$ 4.21
\$5.39 to \$7.32	1,251	7.44 years	\$ 5.86	516	\$ 6.19
\$7.50 to \$8.12	232	4.98 years	\$ 8.21	169	\$ 7.94
	3,064	6.51 years	\$ 4.79	1,979	\$ 4.48

STAAR SURGICAL COMPANY AND SUBSIDIARIES**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS****Years Ended December 30, 2011 and December 31, 2010**

A summary of warrants to purchase Company stock issued to Broadwood as discussed in Note 10 as of December 30, 2011 is presented below:

	Shares (000's)	Weighted- Average Exercise Price	Weighted- Average Remaining Contractual Term	Aggregate Intrinsic Value (000's)
Warrants				
Outstanding at December 31, 2010	1,470	\$ 4.10		
Granted	—	—		
Exercised	—	—		
Forfeited or expired	—	—		
Outstanding at December 30, 2011	1,470	\$ 4.10	2.62	\$ 6,020
Exercisable at December 30, 2011	1,470	\$ 4.10	2.62	\$ 6,020

Note 15 — Commitments and Contingencies***Lease Obligations***

The Company leases certain property, plant and equipment under capital and operating lease agreements. These leases vary in duration and many contain renewal options and/or escalation clauses. Current and long-term obligations under capital leases are included in total current liabilities and total long-term liabilities in the Company's Consolidated Balance Sheets.

Estimated future minimum lease payments under leases having initial or remaining non-cancelable lease terms in excess of one year as of December 30, 2011 were approximately as follows (in thousands):

Operating Capital

Fiscal Year	Leases	Leases
2012	\$ 2,307	\$ 947
2013	2,010	774
2014	1,870	152
2015	1,437	39
2016	1,381	—
Thereafter	—	—
Total minimum lease payments	\$ 9,005	\$ 1,912
Less amounts representing interest	—	(191)
	\$ 9,005	\$ 1,721

Rent expense was approximately \$1.8 million, \$1.8 million, and \$2.2 million for the years ended December 30, 2011, December 31, 2010, and January 1, 2010, respectively (adjusted for Domilens).

The Company had the following assets under capital lease at December 30, 2011 and December 31, 2010 (in thousands):

	2011	2010
Machinery and equipment	\$3,414	\$3,385
Furniture and fixtures	1,255	1,185
Leasehold improvements	133	133
	4,802	4,703
Less accumulated depreciation	3,388	3,033
	\$1,414	\$1,670

STAAR SURGICAL COMPANY AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Years Ended December 30, 2011 and December 31, 2010

Depreciation expense for assets under capital lease for each of the years ended December 30, 2011, December 31, 2010, and January 1, 2010, was approximately \$615,000, \$713,000, and \$1,020,000, respectively.

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.

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 any ultimate amounts that are likely to result from these audits; 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 and certain other officers have as provisions of their employment agreements certain rights, including continuance of cash compensation and benefits, upon a "change in control," which may include an acquisition of substantially all of 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 subject to various claims and legal proceedings arising out of the normal course of our business. These claims and legal proceedings relate to contractual rights and obligations, employment matters, and claims of product liability. STAAR maintains insurance coverage for product liability claims but may not be insured against other potentially material claims. While the Company does not believe that any of the claims known is likely to have a material adverse effect on its financial condition or results of operations, new claims or unexpected results of existing claims could lead to significant financial harm.

Note 16 — Related Party Transactions

The Company has made various advances to certain employees. Amounts due from employees included in prepaids, deposits, and other current assets at December 30, 2011 and December 31, 2010 were \$10,000 and \$93,000, respectively.

Note 17 — Supplemental Disclosure of Cash Flow Information

Interest paid was \$471,000, \$981,000, and \$432,000 for the years ended December 30, 2011, December 31, 2010, and January 1, 2010, respectively. Income taxes paid amounted to approximately \$649,000, \$1,362,000, and \$1,141,000 for the years ended December 30, 2011, December 31, 2010, and January 1, 2010, respectively.

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

Non-cash investing activities and financing activities:	2011	2010	2009
Assets obtained by capital lease	331	940	690
Common stock issued for services	—	—	424
Common stock issued in lieu of vacation	—	—	24
Warrants issued to Broadwood	—	—	290

Note 18 — Basic and Diluted Income Per Share

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

	2011	2010	2009
Numerator:			
Net Income (loss)	\$1,348	\$53	\$(6,200)
Denominator:			
Weighted average common shares and denominator for basic calculation:			
Weighted average common shares outstanding	35,578	34,919	32,569
Less: Unvested restricted stock	(144)	(94)	(71)
Denominator for basic calculation	35,434	34,825	32,498
Weighted average effects of dilutive equity-based compensation awards:			
Employee stock options	859	—	—
Warrants	585	—	—
Denominator for diluted calculation	36,878	34,825	32,498
Net income (loss) per share – basic	\$0.04	\$0.00	\$(0.19)
Net income (loss) per share - diluted	\$0.04	\$0.00	\$(0.19)

For 2010, although the Company reported net income as a result of the gain on sale of Domilens, it used the net loss from continuing operations as the control number in determining whether including potential common shares in the diluted income per share calculation would be dilutive or anti-dilutive.

The following table sets forth (in thousands) the weighted average number of options and warrants to purchase shares of common stock, restricted stock and preferred stock which were not included in the calculation of diluted per share amounts because the effects would be anti-dilutive.

	2011	2010	2009
Options and restricted stock	1,245	3,886	3,863
Warrants	—	70	1,183
Preferred Stock	—	—	1,700
Total	1,245	3,956	6,746

F-31

STAAR SURGICAL COMPANY AND SUBSIDIARIES**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS****Years Ended December 30, 2011 and December 31, 2010****Note 19 — Geographic and Product Data**

The Company markets and sells its products in approximately 60 countries and has manufacturing sites in the United States, Switzerland and Japan. Other than the United States, Japan, Korea, China, and Spain the Company does not conduct business in any country in which its sales in that country exceed 5% of consolidated sales. Sales are attributed to countries based on location of customers. The composition of the Company's sales to unaffiliated customers is set forth below (in thousands):

Net sales to unaffiliated customers	2011	2010	2009
United States	\$13,852	\$14,957	\$16,088
Japan	15,690	13,607	12,884
Korea	8,142	6,082	5,366
China	6,354	3,910	2,855
Others*	18,727	16,402	13,867
Total	\$62,765	\$54,958	\$51,060

*No other location individually exceeds 5% of total sales.

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 IOLs used in cataract surgery and ICLs used in refractive surgery. The composition of the Company's net sales by product line is as follows (in thousands):

Net sales by product line	2011	2010	2009
ICLs	\$32,072	\$24,300	\$21,046

Edgar Filing: STAAR SURGICAL CO - Form 10-K

IOLs	27,547	27,550	26,299
Other surgical products	3,146	3,108	3,715
Total	\$62,765	\$54,958	\$51,060

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

Long-lived assets	2011	2010
U.S	\$1,460	\$1,318
Switzerland	1,010	967
Japan	1,752	1,429
Australia	—	18
Total	\$4,222	\$3,732

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

STAAR SURGICAL COMPANY AND SUBSIDIARIES**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS****Years Ended December 30, 2011 and December 31, 2010****Note 20 — Quarterly Financial Data (Unaudited)**

Summary unaudited quarterly financial data from continuing operations for fiscal 2011 and 2010 is as follows (in thousands except per share data):

December 30, 2011	1st Qtr.	2nd Qtr.	3rd Qtr.	4th Qtr.
Sales	\$ 14,849	\$ 16,269	\$ 15,266	\$ 16,381
Gross profit	9,629	10,861	10,450	11,429
Net income	300	861	77	109
Income per share— basic	0.01	0.02	0.00	0.00
Income per share— diluted	0.01	0.02	0.00	0.00
Net income per share – basic	0.01	0.02	0.00	0.00
Net income per share – diluted	0.01	0.02	0.00	0.00

December 31, 2010	1st Qtr.	2nd Qtr.	3rd Qtr.	4th Qtr.
Sales	\$ 13,778	\$ 13,639	\$ 13,152	\$ 14,389
Gross profit	8,829	8,679	8,260	9,308
Loss from continuing operations	(636)	(1,628)	(1,158)	(691)
Income from discontinued operations, net of taxes	4,166	—	—	—
Net income (loss)	3,530	(1,628)	(1,158)	(691)
Loss per share from continuing operations – basic	(0.02)	(0.05)	(0.03)	(0.02)
Loss per share from continuing operations – diluted	(0.02)	(0.05)	(0.03)	(0.02)
Income per share from discontinued operations, basic and diluted	0.12	—	—	—
Net income (loss) per share – basic	0.10	(0.05)	(0.03)	(0.02)
Net income (loss) per share – diluted	0.10	(0.05)	(0.03)	(0.02)

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

Note 21 — Manufacturing Consolidation Project and Tax Strategy

During 2011 the Company devoted significant resources to two initiatives: a project to consolidate global manufacturing, and development of a strategy to optimize its global organization for tax purposes. The goal of both of these strategies is to continue the Company's improvement in gross profit margin by reducing costs and to position the Company for future growth. STAAR currently manufactures its products in four facilities worldwide. It has developed a plan to methodically consolidate its manufacturing in a single site at its Monrovia, California location by the end of 2013, which is expected subsequently to yield significant savings in cost of goods and to lower its global administrative costs and reduce income taxes.

The Company expects these initiatives to cost approximately \$6 million over a three-year period, of which it incurred approximately \$1.1 million during 2011. These expenses are included in other general and administrative expenses in the consolidated statement of operations for the year ended December 30, 2011. Expenditures to date have largely consisted of professional fees to advisors and consultants. The Company also expects to spend approximately \$2.4 million in capital expenditures to consolidate its manufacturing.

A summary of the activity for these initiatives is presented below as of December 30, 2011 (in thousands):

	Termination Benefits	Other Associated Costs	Total
Liability at December 31, 2010	\$—	\$—	\$—
Costs incurred and charged to expense	36	1,024	1,060
Cash payments	—	(931) (931)
Liability at December 30, 2011	\$36	\$93	\$129
Total costs incurred to date	\$36	\$1,024	\$1,060
Total costs expected to be incurred	\$1,474	\$4,526	\$6,000

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Stockholders

STAAR Surgical Company

Monrovia, CA

The audits referred to in our report dated March 8, 2012 relating to the consolidated financial statements of STAAR Surgical Company and Subsidiaries, which is contained in Item 8 of this Form 10-K, also included the audit of the financial statement schedule contained in Schedule II. This financial statement schedule is the responsibility of the Company's management. Our responsibility is to express an opinion on the financial statement schedule based on our audits.

In our opinion such financial statement schedule, when considered in relation to the basic consolidated financial statements taken as a whole, presents fairly, in all material respects, the information set forth therein.

/s/ BDO USA, LLP
Los Angeles, California
March 8, 2012

STAAR SURGICAL COMPANY AND SUBSIDIARIES

SCHEDULE II — VALUATION AND QUALIFYING ACCOUNTS AND RESERVES

Column A	Column B	Column C	Column D	Column E
Description	Balance at Beginning of Year	Additions	Deductions	Balance at End of Year
	(In thousands)			
2011				
Allowance for doubtful accounts and sales returns deducted from accounts receivable in balance sheet	\$1,423	\$ 195	\$ 489	\$1,128
Deferred tax asset valuation allowance	51,689	—	118	51,571
	\$53,112	\$ 195	\$ 607	\$52,699
2010				
Allowance for doubtful accounts and sales returns deducted from accounts receivable in balance sheet	\$1,332	\$ 410	\$ 319	\$1,423
Deferred tax asset valuation allowance	50,801	888	—	51,689
	\$52,133	\$ 1,298	\$ 319	\$53,112
2009				
Allowance for doubtful accounts and sales returns deducted from accounts receivable in balance sheet	\$846	\$ 612	\$ 126	\$1,332
Deferred tax asset valuation allowance	47,708	3,093	—	50,801
	\$48,554	\$ 3,705	\$ 126	\$52,133