STAAR SURGICAL CO
Form 424B5
April 26, 2007

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Filed Pursuant to Rule 424(b)(5) and Rule 462(b)
Registration No. 333-136213
and Registration No. 333-142374

PROSPECTUS SUPPLEMENT
(to Prospectus Dated August 8, 2006)

STAAR Surgical Company

3,130,435 Shares of Common Stock

We are offering 3,130,435 shares of our common stock pursuant to this prospectus supplement and the accompanying prospectus.

Our common stock is traded on the Nasdaq Global Market under the trading symbol STAA. On April 25, 2007, the last reported price of our common stock on the Nasdaq Global Market was $5.01.

Investment in our common stock involves a high degree of risk. Please carefully consider the Risk Factors described beginning on page S-7 of this prospectus supplement.

	Per Share	Total
Public offering price	$ 5.00	$ 15,652,175.00
Underwriting discounts and commissions	$ 0.30	$ 939,130.50
Proceeds, before expenses, to STAAR Surgical Company	$ 4.70	$ 14,713,044.50

The underwriter may also purchase up to an additional 469,565 shares of our common stock from us at the public offering price, less the underwriting discounts and commissions, within 30 days from the date of this prospectus supplement to cover any over-allotments.

Delivery of the shares will be made on or about May 1, 2007.

Neither the Securities and Exchange Commission, nor any state securities commission, has approved or disapproved of these securities or passed upon the adequacy or accuracy this prospectus supplement or the

accompanying prospectus. Any representation to the contrary is a criminal offense.

Pacific Growth Equities, LLC

The date of this prospectus supplement is April 25, 2007.

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Prospectus Supplement

Prospectus

You should rely only on the information contained in this prospectus supplement and the accompanying prospectus and information to which we have referred you. We have not authorized anyone else to provide you with different information. In particular, we have not authorized any dealer or salesperson to give any information or to represent anything not contained in this prospectus. You must not rely on any unauthorized information or representation. This prospectus supplement is an offer to sell only the securities it specifically describes on the front of the document, and only under circumstances and in jurisdictions where we can lawfully do so. You should assume that the information in

this prospectus supplement and the prospectus is accurate only as of the date on the front of the document. Any information we have incorporated by reference is accurate only as of the date of the document incorporated by reference, regardless of the time this prospectus supplement is delivered or the time a security is sold.

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ABOUT THIS PROSPECTUS SUPPLEMENT

This prospectus supplement and the accompanying prospectus dated August 8, 2006 are part of a registration statement on Form S-3 (File No. 333-136213) we filed with the Securities and Exchange Commission using a shelf registration process. Under this shelf registration process, we may from time to time sell securities described in the accompanying prospectus in one or more offerings. This document consists of two parts. The first part is this prospectus supplement, which describes the specific terms of our common stock offering. The second part is the accompanying prospectus, which provides more general information. This prospectus supplement and the accompanying prospectus include important information about us, our common stock and other information you should know before investing. This prospectus supplement also adds, updates and changes information in the accompanying prospectus.

You should rely only on the information in this prospectus supplement and the accompanying prospectus or documents to which we otherwise refer you. Neither we nor the underwriter have authorized anyone to provide you with different information. If anyone provides you with different or inconsistent information, you should not rely on it. If the information in this prospectus supplement or any free writing prospectus we may authorize to be delivered to you differs in any way from the information contained in the accompanying prospectus, you should rely on the information in this prospectus supplement or the free writing prospectus. Before purchasing our common stock, you should carefully read this prospectus supplement, and the accompanying prospectus together with the additional information about us described under *Where You Can Find More Information* and *Incorporation of Documents by Reference* in the accompanying prospectus.

You should assume that the information in this prospectus supplement is accurate only as of the date on the cover page, and that the information in the accompanying prospectus is accurate only as of the date on its cover page. Any information we have incorporated by reference in this prospectus supplement is accurate only as of the date of the document incorporated by reference, unless we indicate otherwise. Our business, financial condition, results of operations and prospects may have changed materially since that date.

This prospectus supplement and the accompanying prospectus do not constitute an offer to sell, or a solicitation of an offer to purchase, the securities offered by this prospectus supplement and the accompanying prospectus in any jurisdiction to or from any person to whom or from whom it is unlawful to make such offer or solicitation of an offer in such jurisdiction.

We further note that any representations, warranties and covenants we may have made in any agreement filed as an exhibit to any document incorporated by reference in the accompanying prospectus were made solely for the benefit of the parties to that agreement, including, in some cases, for the purpose of allocating risk among the parties to the agreement. You should not deem these to be representations, warranties or covenants to you. Moreover, such representations, warranties or covenants were accurate only as of the date when made. Accordingly, you should not rely on such representations, warranties and covenants as accurately representing the current state of our affairs.

Unless the context otherwise requires, the terms we, our or us and STAAR refer to STAAR Surgical Company and subsidiaries.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

Statements in this prospectus supplement that are not statements of historical fact are forward-looking statements. Forward-looking statements also appear in the prospectus and the other documents to which we refer you in this prospectus supplement and the prospectus. They may be found, among other places, in the sections entitled Business and Management s Discussion and Analysis of Financial Condition and Results of Operations in our most recent report

on Form 10-K, in our quarterly reports on Form 10-Q, and amendments to these documents filed with the SEC. These statements relate to our future plans, objectives, expectations and intentions. Among other things, forward-looking statements include statements about the following:

our strategy;

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our business prospects including, expectations for revenue or other performance of our business or of specific products;

the status of applications for approval of products by the FDA or regulatory agencies of other countries;

sufficiency of our cash reserves;

product development;

research and development and other expenses; and

legal risks.

You may also generally identify forward-looking statements by the use of words such as expect, anticipate, intend, plan and similar expressions.

You should not place undue reliance on our forward-looking statements. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of numerous risks and uncertainties that are beyond our control, including those we discuss in Risk Factors and elsewhere in this prospectus supplement, in the accompanying prospectus and in our other reports we file with the SEC. The forward-looking statements in this prospectus supplement speak only as of the date shown on the cover page, and you should not rely on these statements without also considering the risks and uncertainties associated with these statements and our business.

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PROSPECTUS SUMMARY

This summary highlights selected information contained elsewhere or incorporated by reference in this prospectus supplement and the accompanying prospectus. This summary may not contain all the information that you should consider before investing in our common stock. You should read the entire prospectus supplement and the accompanying prospectus carefully, including Risk Factors contained in this prospectus supplement and the financial documents incorporated by reference in the accompanying prospectus, before making an investment decision. This prospectus supplement may add to, update or change information in the accompanying prospectus.

STAAR Surgical Company develops and manufactures visual implants and other innovative ophthalmic products to improve or correct the vision of patients with cataracts and refractive conditions. We distribute our products worldwide.

Cataract Surgery

Most of our revenue is generated by manufacturing and selling foldable intraocular lenses, known as IOLs, and related products for cataract surgery. A foldable IOL is a prosthetic lens used to replace a cataract patient s natural lens after it has been extracted in minimally invasive small incision cataract extraction. STAAR makes IOLs out of silicone and out of Collamer®, STAAR s proprietary biocompatible collagen copolymer lens material. STAAR s IOLs are available in both three-piece and one-piece designs. Over the years, we have expanded our range of products for use in cataract surgery to include the following:

The silicone Toric IOL, used in cataract surgery to treat preexisting astigmatism;

The Preloaded Injector, a three-piece silicone IOL preloaded into a single-use disposable injector;

STAARVISC™ II, a viscoelastic material which is used as a tissue protective lubricant and to maintain the shape of the eye during surgery;

STAAR SonicWAVE™ Phacoemulsification System, a medical device system used to remove a cataract patient s cloudy lens through a small incision using ultrasound and suction. STAAR s SonicWAVE system features low energy and high vacuum characteristics; and

Cruise Control, a disposable filter which allows for a faster, cleaner phacoemulsification procedure and is compatible with all phacoemulsification equipment utilizing Venturi and peristaltic pump technologies.

Refractive Surgery

Manufacturing and selling lenses for refractive surgery is an increasingly important source of revenue for STAAR. We have used our proprietary biocompatible Collamer material to develop and manufacture implantable Collamer lenses, or ICLs. STAAR s VISIAN™ ICL and VISIAN™ Toric ICL, or TICL™, treat refractive disorders such as myopia (near-sightedness), hyperopia (far-sightedness) and astigmatism. These disorders of vision affect a large proportion of the population. Unlike the IOL, which replaces a cataract patient s cloudy lens, these products are designed to work with the patient s natural lens to correct refractive disorders. The surgeon implants the foldable Visian lens through a tiny incision, generally under local anesthesia. STAAR began selling the Visian ICL outside the U.S. in 1996 and the Visian TICL in 2002. These products are sold in more than 40 countries. STAAR s goal is to establish the position of the ICL and TICL throughout the world as a primary choice for refractive surgery.

The U.S. Food and Drug Administration, or FDA, approved the Visian ICL for the treatment of myopia in the U.S. in December 2005. While the U.S. roll-out of the ICL remains in its earliest stage, we believe that the ICL will be a viable choice for refractive surgery and could replace cataract surgery products as STAAR s largest source of revenue. The ICL and TICL are approved for use in countries that require the European Union CE Mark and in Korea, Singapore, and Canada. The ICL is also approved in China, where an application for the TICL is pending. Applications are also pending in Australia, and we are working to obtain

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new approvals for the ICL and TICL in other countries. We submitted our application for U.S. approval of the TICL to the FDA in 2006.

Other products

We have also developed the AquaFlow™ Collagen Glaucoma Drainage Device (the Aqua Flow Device), as an alternative to current methods of treating open-angle glaucoma. The AquaFlow Device is implanted in the sclera (the white of the eye), using a minimally invasive procedure, for the purpose of reducing intraocular pressure.

We also sell other instruments, devices and equipment that we manufacture or that are manufactured by others in the ophthalmic industry. In general, these products complement STAAR s proprietary product range and are intended to allow us to compete more effectively.

Recent Developments

On April 23, 2007, we announced our preliminary financial results for the first fiscal quarter 2007. We expect total revenue for the first fiscal quarter 2007 to be approximately $14.9 million.

Corporate Information

Originally incorporated in California in 1982, STAAR reincorporated in Delaware in 1986. Our executive offices are located at 1911 Walker Avenue, Monrovia, California 91016, and our telephone number is (626) 303-7902. Our website address is www.staar.com. The information on our website is not a part of this prospectus.

STAAR Surgical Company, STAAR s Logo, Visian®, Collamer®, STAARvisc™, SonicWAVE™ and AquaFlow™ are trademarks of STAAR in the U.S. and other countries. Collamer® is the brand name for STAAR s proprietary collagen copolymer lens material.

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The Offering

Common stock offered	3,130,435 shares
Common stock to be outstanding after this offering	28,812,565 shares
Use of Proceeds	We intend to use the net proceeds of this offering for general corporate purposes, including the repayment of $4 million of our outstanding indebtedness, expansion of sales and marketing, working capital, capital expenditures, technology acquisition and continuing research and development.
Nasdaq Global Market symbol	STAA
Risk Factors	You should read the Risk Factors section of the prospectus supplement and the other information included or incorporated by reference in this prospectus supplement and the accompanying prospectus for a discussion of factors you should carefully consider before deciding to invest in shares of our common stock.

Except as otherwise indicated, the number of shares to be outstanding after this offering throughout this prospectus supplement is based on 25,682,130 shares outstanding on April 23, 2007, and excludes:

- 3,703,400 shares of common stock issuable upon the exercise of outstanding stock options as of April 23, 2007, with a weighted average exercise price of $6.79 per share;
- 70,000 shares of common stock issuable upon the exercise of outstanding warrants as of March 31, 2007, with an exercise price of $6.00 per share; and
- 714,210 shares available for future issuance under our 2003 Omnibus Equity Incentive Plan.

In addition, except as otherwise indicated, the information throughout this prospectus supplement assumes no exercise by the underwriter of its over-allotment option to purchase up to 469,565 additional shares of common stock from us in the offering.

Dividend Policy

We intend to retain any future earnings to finance the growth and development of our business and do not anticipate paying any cash dividends in the foreseeable future. During the term of our credit agreement with Wells Fargo Bank we may not pay dividends to stockholders without its consent.

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RISK FACTORS

Investment in our securities involves a high degree of risk. You should carefully consider the risks described below, as well as the risks described in the documents incorporated by reference in this prospectus supplement and the accompanying prospectus, before making a decision to invest in the common stock. These risks are not the only ones we face. The trading price of the common stock could decline due to any of these risks, and you may lose all or part of your investment. This prospectus supplement, the accompanying prospectus and the documents to which they refer you also contain forward-looking statements that involve risks and uncertainties. Actual results could differ materially from those anticipated in these forward-looking statements as a result of factors beyond our control, including the risks faced by us described below and in the documents incorporated herein by reference.

Risks Related to Our Business

We have a history of losses and anticipate future losses.

We have reported losses in each of the last several fiscal years and have an accumulated deficit of $86.7 million as of December 29, 2006. There can be no assurance that we will report net income in any future period.

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

Our cash requirements continue to exceed the level of cash generated by operations and we expect to continue to seek additional resources to support and expand our business, such as debt or equity financing. Because of our history of losses and negative cash flows, our ability to obtain adequate financing on satisfactory terms is limited. 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. An inability to secure additional financing could prevent the expansion of our business and jeopardize our ability to continue operations.

Our history of losses limits our access to credit and increases the risk of a default on our loan agreements.

Under our U.S. and international bank credit facilities and lease lines of credit, we had $3 million in outstanding indebtedness and $1.4 million available for borrowing as of December 29, 2006. The credit facilities are subject to various financial covenants. If our losses continue we risk defaulting on the terms of our credit arrangements. Our limited borrowing capacity could cause a shortfall in working capital or prevent us from making expenditures that are essential to our business. To the extent we borrow under our credit facilities, a subsequent default could cause our obligations to be accelerated, result in the assessment of default interest or penalties, make further borrowing difficult or impracticable and jeopardize our ability to continue operations.

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

We have accumulated approximately $37.4 million of tax loss carryforwards to be used in future periods if we become profitable. 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 we become profitable.

FDA compliance issues have harmed our reputation, 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.

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Based on the results of the FDA inspections of STAAR s Monrovia, California facilities in 2005 and 2006, STAAR believes that it is substantially in compliance with the FDA s Quality System Regulations and Medical Device Reporting regulations. However, between December 29, 2003 and July 5, 2005 we received Warning Letters and other correspondence indicating that the FDA found STAAR s Monrovia, California facility in violation of applicable regulations, warning of possible enforcement action and suspending approval of new implantable devices. The FDA s findings of compliance deficiencies during that period harmed our reputation in the ophthalmic industry, affected our product sales and delayed FDA approval of the ICL.

At the March 14, 2007 conclusion of an audit of STAAR s clinical trial records by the Bioresearch Monitoring Program of the FDA Office of Regulatory Affairs, or BIMO, STAAR received eight Inspectional Observations on FDA Form 483 noting noncompliance with regulations. BIMO s oversight covers clinical research, rather than the manufacturing, quality and device reporting issues that have been STAAR s greatest focus in its recent compliance initiatives. If our efforts to promptly address the Inspectional Observations through voluntary corrective action are not successful, the FDA would take further action that could reduce or curtail our ability to sponsor clinical studies and use such studies to secure new product approvals.

STAAR s ability to continue its U.S. business depends on the continuous improvement of its quality systems and its compliance with FDA regulations. Accordingly, for the foreseeable future STAAR s management expects its strategy to include devoting 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.*

Our strategy to restore profitability in the near term relies on successfully penetrating the U.S. refractive market.

While products to treat cataracts continue to account for the majority of our revenue, we believe that increased income generated by sales of our Visian ICL refractive products, especially in the U.S., presents a near term opportunity for a return to profitability. The FDA approved the Visian ICL for treatment of myopia on December 22, 2005. Selling and marketing the ICL has presented a challenge to our sales and marketing staff and to our independent manufacturers representatives. In the U.S. patients who might benefit from the ICL have already been exposed to a great deal of advertising and publicity about laser refractive surgery, but have little if any awareness of the ICL. In addition, established refractive surgeons frequently have large and well developed practices that are oriented entirely toward the delivery of laser procedures. In countries where the ICL has been approved, our sales have grown steadily but slowly, and the U.S. appears to be following this pattern. A surgeon interested in implanting the ICL must first schedule training and certification and invest time in the training process. While STAAR has sufficient resources to make training available to qualified surgeons with minimal delay, the need to undergo training continues to limit the pace at which interested surgeons can begin providing the ICL to their patients. STAAR employs advertising and promotion targeted to potential patients through providers, but has limited resources for these purposes. Failure to successfully market the ICL in the U.S. will delay and may prevent growth and profitability.

Our core domestic business has suffered declining sales, which sales of new products have only begun to offset.

The foldable silicone IOL remains our largest source of sales. Since we introduced the product, however, competitors have introduced IOLs employing a variety of designs and materials. Over the years these products have taken an increasing share of the IOL market, while the market share for STAAR silicone IOLs has decreased. In particular, many surgeons now choose lenses made of acrylic material rather than silicone for their typical patients. In addition,

our competitors have begun to offer multifocal or accommodating lenses that claim to reduce the need for cataract patients to use reading glasses; the market for these presbyopic lenses is expected to grow as a segment of the cataract market. Our newer line of IOLs made of our proprietary

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biocompatible Collamer material, while intended to reverse the trend of declining domestic cataract product sales, may not permit us to recover the market share lost over the last several years.

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. For example, in fiscal year 2006, strikes and slow-downs by doctors in Germany were partly responsible for a drop in sales by our wholly owned subsidiary Domilens GmbH, which distributes ophthalmic products in Germany. Such problems could occur again in Germany or other regions and, 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 revenue and earnings.

Our sales are subject to significant seasonal variation.

We generally experience lower sales during the third quarter due to the effect of summer vacations on elective procedures. In particular, because sales activity in Europe drops dramatically in July and August, and European sales have recently accounted for a greater proportion of our total sales, this seasonal variation in our results has become even more pronounced.

We depend on independent manufacturers representatives.

In an effort to manage costs and bring our products to a wider market, we have entered into long-term agreements with independent regional manufacturers representatives, who introduce our products to eye surgeons and provide the training needed to begin using some of our products. Under our agreements with these representatives, each receives a commission on all of our sales within a specified region, including sales on products we sell into their territories without their assistance. Because they are independent contractors, we have a limited ability to manage these representatives or their employees. In addition, a representative may represent manufacturers other than STAAR, although not in competing products. STAAR s strategy for growth involves the marketing of innovative products like the ICL, Collamer IOLs, Toric IOLs and the AquaFlow Device. We have relied on the independent representatives to implement the marketing of these products and to sustain the market for our more established products. Because our independent representatives generally have little experience dealing with surgeons who specialize in refractive procedures, we have faced greater challenges in developing the domestic market for the ICL. If our independent manufacturers representatives do not devote sufficient resources to marketing our products, or if they lack the skills or resources to market our new products, our new products will fail to reach their full sales potential and sales of our established products could decline.

Product recalls have been costly and may be so in the future.

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 our products may not come to light until after the products are sold or consigned. In those circumstances, we have previously made voluntary recalls of our products. We may also be subject to recalls initiated by manufacturers of products we distribute. In February 2006, our German subsidiary recalled all lots of a balanced salt solution it distributes due to the manufacturer s recall for possible endotoxin content. In 2005, we recalled one lot of phaco tubing manufactured by a third party, due to incorrect labeling, and we recalled one lot of STAARVISC, also manufactured by a third party, due to a potential sterility breach of the packaging of the cannula that is packaged with the STAARVISC. The last recall of a product

manufactured by STAAR took place during 2004, when we initiated several voluntary recalls including 33 lots of IOL cartridges, three lots of injectors, and 529 lenses, and in February 2004, in an action considered a recall but with no requirement for product to be returned to us, we issued a letter to healthcare professionals advising them of the potential for a change in

manifest refraction over time in rare cases involving the single-piece Collamer IOL. We believe recalls have harmed our reputation and adversely affected our product sales, although the impact cannot be quantified. Similar recalls could take place again. Courts or regulators can also impose mandatory recalls on us, even if we believe our products are safe and effective.

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.

We could experience losses due to product liability claims.

We have been subject to product liability claims in the past and continue to be so. Our third-party product liability insurance coverage has become more expensive and difficult to procure. 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 in excess of applicable insurance could have a material adverse effect on our business, financial condition and results of operations. Even if any product liability loss is covered by an insurance policy, these policies have retentions or deductibles that provide that we will not receive insurance proceeds until the losses incurred exceed the amount of those retentions or deductibles. To the extent that any losses are below these retentions or deductibles, we will be responsible for paying these losses. 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 compete with much larger companies.

Our competitors, including Alcon, Advanced 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.

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

We manufacture all of our products either at our facilities in California or at our facility in Switzerland. 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.

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

Our products are sold in approximately 50 countries. Sales from international operations make up a significant portion of our total sales. For the year ended December 29, 2006, sales from international operations were 60% of our total

sales. The results of operations and the financial position of certain of our offshore 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 expenses are incurred in a different

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currency from the currency in which our sales are received. Our most significant currency exposures are to the Euro, the Swiss Franc, and the Australian dollar. 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. are subject to a number of risks and potential costs, including lower profit margins, less stringent protection of intellectual property and 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.

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 and language differences can result in misunderstandings among internationally dispersed personnel. The risk that unauthorized conduct may go undetected will always be greater in foreign subsidiaries. For example, in early 2007 STAAR learned that the president of its German sales subsidiary, Domilens, had misappropriated corporate assets. Some countries may also have laws or cultural factors that make it difficult to impose uniform standards and practices. For example, while STAAR s Code of Ethics requires all employees to certify they are not aware of code violations by others, German legal counsel has advised STAAR that in Germany it cannot legally compel ordinary employees (that is, non-supervisors) to notify STAAR of breaches by others. STAAR believes the absence of such a requirement in its Code of Ethics for German employees is a risk inherent to doing business in Germany that may be mitigated, but not entirely eliminated, by other controls.

We obtain some of the components of our products from a single source, and an interruption in the supply of those components could reduce our sales.

We obtain some of the components for our products from a single source. For example, only one supplier produces our viscoelastic product. The loss or interruption of any of these suppliers could increase costs, reducing our sales and profitability, or harm our customer relations by delaying product deliveries. Even when substitute suppliers are available, the need to certify regulatory compliance and quality standards of substitute suppliers could cause significant delays in production and a material reduction in our sales. Even when secondary sources are available, 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.

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

Our manufacturing, research and development practices involve the use of hazardous materials. We are subject to federal, state and local laws and regulations in the various jurisdictions in which we have operations governing the use, manufacturing, storage, handling and disposal of these materials and certain waste products. 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 a major 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.

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We risk losses through litigation.

From time to time we are party 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. While we do not believe that any of the claims known to us is likely to have a material adverse effect on our financial condition or results of operations, new claims or unexpected results of existing claims could lead to significant financial harm.

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 have licensed our technology to our joint venture company which could cause our joint venture company to become a competitor.

We have granted to our Japanese joint venture, Canon Staar Co. Inc., an irrevocable, exclusive license to make, have made and sell products using our technology in Japan. We have also granted Canon Staar an irrevocable, exclusive license to make and have made products using our technology in China and to sell such products made in China in China and Japan. In addition, we have granted Canon Staar an irrevocable, non-exclusive license to sell products using our technology in the rest of the world. It is the intent of the Joint Venture Agreement that products be marketed indirectly through Canon, Inc., Canon Marketing Japan Inc., their subsidiaries, STAAR, and other distributors that the Canon Staar Board approves. The grant of such licenses and rights under STAAR s technology may result in Canon Staar becoming a competitor of STAAR, which could materially reduce STAAR s revenues and profits. See *Business Canon Staar Joint Venture.*

Our interest in Canon Staar may be acquired for book value on the occurrence of specified events, including a change in control of STAAR.

If STAAR becomes insolvent or enters bankruptcy, dissolves, enters into a merger or other reorganization, is the subject of a take-over attempt or experiences other events of default under the joint venture agreement, the other joint venture partners will have the right to acquire STAAR s interest in Canon Staar at book value. Book value of STAAR s 50% interest in Canon Staar was $3.6 million as of December 31, 2006. Book value may not represent the fair value of STAAR s interest in Canon Staar, and depending on the future condition of Canon Staar s business it may represent only a small fraction of fair value. STAAR s interest in Canon Staar is valued in Japanese yen and its value in U.S. dollars may vary significantly with fluctuations in currency exchange rates. See *Business Canon Staar Joint Venture*.

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 result in significant change to our reported results of operation or financial condition.

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.

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

We depend on the continuing operation of all of our manufacturing facilities in California and Switzerland, which have little redundancy or overlap among their activities. Our facilities are subject to catastrophic loss due to fire, flood, earthquake, terrorism or other natural or man-made disasters. Our California 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. Our insurance for property damage and business interruption may not be sufficient to cover any particular loss, and we do not carry insurance or reserve funds for interruptions or potential losses arising from earthquakes or terrorism.

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 are significantly dependent on information technology networks and systems, including the Internet, to process, transmit and store electronic information. In particular, we depend on our information technology infrastructure for 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.

Risks Related to the Ophthalmic Products Industry

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

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. For example, glaucoma requires ongoing treatment over a long period; thus, many doctors are reluctant to switch a patient to a new treatment if the patient s current treatment for glaucoma remains effective. This has been a challenge in selling our AquaFlow Device.

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

We spent 12.6% of our sales on research and development during the year ended December 29, 2006, and we expect to spend approximately 10% 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.

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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 in the U.S. and Europe. 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. In some countries government agencies control costs by limiting the number of surgical procedures they will reimburse. For example, a recent reduction in the number of authorized cataract procedures in Germany has affected the sales of our German subsidiary, Domilens. Similar changes could occur in our other markets. The U.S. Congress has considered 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, which increases our costs and could prevent us from selling our products.

STAAR is regulated by regional, national, state and local agencies, including 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 also subject to government regulation over the prices we charge and the rebates we offer to customers. Complying with government regulation substantially increases the cost of developing, manufacturing and selling our products.

In the U.S., we must obtain approval from the FDA for each product that we market. Competing in the ophthalmic products industry requires us to introduce new or improved products and processes continuously, and to submit these to the FDA for approval. Obtaining FDA approval is 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.

Regulatory investigations and allegations, whether or not they lead to enforcement action, 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

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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.

As a result of widespread concern about backdating of stock options and similar conduct among U.S. public companies, during 2006 and early 2007 STAAR conducted an investigation of its practices from 1993 to the present in granting stock options to employees, directors and consultants. STAAR s investigation did not find evidence of fraud, deliberate backdating or similar practices. The investigation did uncover evidence of frequent administrative errors and delays, which STAAR investigated further and determined would not have a material effect on its historical financial statements, either individually or in aggregate. STAAR believes that its investigation, while limited in scope, was reasonably designed to detect fraud and backdating and determine any material effect on its financial statements. However, STAAR cannot ensure that a more exhaustive investigation would not find additional errors or irregularities in option granting practices, the effect of which could be material.

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. 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 can be costly, time-consuming and disruptive to our business.

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

We rely on contractual provisions, confidentiality procedures and patent, trademark, copyright and trade secrecy 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 o