

STAAR SURGICAL CO  
Form 8-K  
April 26, 2007

**UNITED STATES SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549  
FORM 8-K  
CURRENT REPORT**

**Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**

Date of Report (Date of Earliest Event Reported): April 25, 2007

**STAAR Surgical Company**

(Exact name of registrant as specified in its charter)

Delaware	0-11634	95-3797439
(State or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)
1911 Walker Ave, Monrovia, California		91016
(Address of principal executive offices)		(Zip Code)

Registrant's telephone number, including area code: 626-303-7902

Not Applicable

Former name or former address, if changed since last report

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
  - Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
  - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
  - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
-

### **Item 1.01 Entry into a Material Definitive Agreement**

On April 25, 2007, the Company entered into an Underwriting Agreement with Pacific Growth Equities, LLC, providing for the underwritten public offering of 3,130,435 million shares of its common stock at a price to the public of \$5.00 per share, subject to customary closing conditions. The gross proceeds of the offering, before deducting 6% underwriting commissions and estimated offering expenses, are expected to be approximately \$15.65 million. All shares of the common stock offered by STAAR are being sold pursuant to a shelf registration statement that was declared effective by the U.S. Securities and Exchange Commission on August 8, 2006. In the Underwriting Agreement, STAAR has also granted the underwriter an option to purchase up to an additional 469,565 shares of its common stock to cover over-allotments, if any. The offering is expected to close on May 1, 2007. The Underwriting Agreement is filed as Exhibit 1.1 to this report, and the foregoing description of the material terms of the Underwriting Agreement is qualified in its entirety by reference to such exhibit.

The offering of these shares of common stock described above may be made only by means of a prospectus supplement to the prospectus contained in the registration statement, which is also called the base prospectus. Such prospectus supplement, which incorporates the base prospectus, will be filed with the SEC, and be available on the SEC's website at <http://www.sec.gov>.

### **Item 8.01 Other Events**

#### **RISK FACTORS**

Investment in our securities involves a high degree of risk. You should carefully consider the risks described below 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.

STAAR Surgical Company has revised its Risk Factors and the description of its business.

#### **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.

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

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

Edgar Filing: STAAR SURGICAL CO - Form 8-K

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

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.

***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.

***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.





***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

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 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. 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. 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 and contractual obligations 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 contractual obligations, including with respect to Canon Staar, could discourage a potential acquisition of our company. 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; 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 preventing changes in our management.

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

Our stock price has fluctuated widely, ranging from \$5.30 to \$9.50 during the twelve month period ended March 30, 2007. Our stock price will likely continue to fluctuate in response to factors such as 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.



***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. Sales of common or preferred stock 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.

## **BUSINESS**

### **Background**

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 iris is a 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 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 retina is a layer of nerve tissue 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 and in front of the natural lens, is filled with a watery fluid called the aqueous humor, while the portion of the eye behind the lens is filled with a jellylike material called the vitreous humor. 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.

Common visual disorders, disease or trauma can affect the eye. The most prevalent ocular disorders or diseases are cataracts and glaucoma. Cataracts generally form through an age-related process whereby the natural crystalline lens hardens and loses its transparency, impairing visual acuity.

Refractive disorders, which are generally 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 condition caused by the loss of elasticity of the natural crystalline lens, reducing the eye's ability to accommodate or adjust its focus for varying distances.

### **History**

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 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. The ICL received CE Marking in 1997, permitting sales in countries that require the CE Mark, and it received FDA approval for the treatment of myopia in the U.S. in December 2005. We now sell the ICL in more than 40 countries and it has been implanted in more than 65,000 eyes worldwide.

Other milestones in STAAR's history include the following:



Edgar Filing: STAAR SURGICAL CO - Form 8-K

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 venture into the refractive market in the United States.

In 2000, STAAR introduced an IOL made of the Collamer material, making its clarity, refractive qualities, and biocompatibility available to cataract patients and their surgeons.

In 2001, STAAR commenced commercial sales of the 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 CE Mark. The TICL is not yet approved for commercial sale in the U.S.

In late 2003, STAAR, through its Japanese joint venture company, Canon Staar, introduced the first preloaded 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 ICL for the treatment of myopia, making it the first small incision phakic implant commercially available in the United States.

### **Financial Information about Segments and Geographic Areas**

STAAR's principal products are IOLs and ancillary products used in cataract and refractive surgery. Because we generate 100% of our sales from the ophthalmic surgical product segment, we operate as one operating segment for financial reporting purposes.

### **Principal Products**

We design our products with 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.

*Intraocular Lenses (IOLs) and Related Cataract Treatment Products.* We produce and market a line of foldable IOLs for use in minimally invasive cataract surgical procedures.

Because our IOLs fold, surgeons can implant our IOLs into the eye through an incision as small as 2.8 mm. Once inserted, the IOL unfolds naturally to replace the cataractous lens.

We currently manufacture foldable IOLs from both our proprietary Collamer material and silicone. We make IOLs in each of the materials in two different configurations: the single-piece plate haptic design, and the three-piece design where the optic is combined with spring-like Polyimide™ loop haptics. The selection of one style over the other is primarily based on the preference of the ophthalmologist.

We have developed and currently market globally 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. The Toric IOL is the first refractive product we offered in the U.S.

In late 2003, we introduced through our joint venture company, Canon Staar, the first preloaded lens injector system in international markets. The Preloaded Injector is a disposable lens delivery system containing a three-piece silicone IOL that is sterilized and ready for implant. We believe the Preloaded Injector offers surgeons improved convenience and reliability. The Preloaded Injector is not yet available in the U.S. In 2006 Canon Staar began selling in Japan an acrylic-lens-based Preloaded Injector employing a lens supplied by Nidek Co., Ltd.

Sales of IOLs accounted for approximately 46% of our total revenues for the 2006 fiscal year, 52% of total revenues for the 2005 fiscal year and 56% of total revenues for the 2004 fiscal year.

As part of our approach to providing complementary products for use in minimally invasive cataract surgery, we also market STAARVISC II, a viscoelastic material which is used as a protective lubricant and to maintain the shape of the eye during surgery, the STAARSonicWAVE Phacoemulsification System, a medical device system that uses ultrasound to remove a cataract patient's cloudy lens through a small incision and has low energy and high vacuum characteristics, and Cruise Control, a single-use disposable filter which allows for a faster, cleaner phacoemulsification procedure and is compatible with all phacoemulsification equipment utilizing Venturi and peristaltic pump technologies. We also sell other related instruments, devices, surgical packs and equipment that we manufacture or that are manufactured by others. Sales of other cataract products accounted for approximately 31% of our total revenues for the 2006 fiscal year, 36% of total revenues for the 2005 fiscal year and 32% of total revenues for the 2004 fiscal year.

*Refractive Correction Visian ICL.* ICLs are implanted into the eye to correct refractive disorders 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 is capable of correcting refractive errors over a wide diopter range.

The ICL is folded and implanted into the eye behind the iris and in front of the natural crystalline lens using minimally invasive surgical techniques similar to implanting an IOL during cataract surgery, except that the natural lens is not removed. The surgical procedure to implant the ICL is typically performed with topical anesthesia on an outpatient basis. Visual recovery is usually within one to 24 hours.

We believe the ICL will complement current refractive technologies and allow refractive surgeons to expand their treatment range and customer base.

The FDA approved the ICL for myopia for use in the United States on December 22, 2005. The ICL and TICL are approved in countries that require the Conformité Européenne Mark (or CE Mark) Canada, Korea and Singapore. Applications are pending in China and Australia, and STAAR is working to obtain new approvals for the ICL and TICL in other countries. STAAR submitted its application for U.S. approval of the TICL to the FDA in 2006.

The Hyperopic ICL, for treatment of far-sightedness or hyperopia, is approved for use in countries that require the CE Mark and in Canada, and is currently in clinical trials in the United States.

The ICL is available for myopia in the United States in four lengths and 27 powers for each length, and internationally in four lengths, with 41 powers for each length, and for hyperopia in four lengths, with 37 powers for each length, which equates to 420 inventoried parts. This requires STAAR to carry a significant amount of inventory to meet the customer demand for rapid delivery. The Toric ICL is available for myopia in the same powers and lengths but carries additional parameters of cylinder and axis with 11 and 180 possibilities, respectively. Accordingly, the Toric ICL is generally made to order.

Sales of ICLs (including TICLs) accounted for approximately 22% of our total revenues for the 2006 fiscal year, 10% of total revenues for the 2005 fiscal year and 8% of total revenues for the 2004 fiscal year.

## **Other Products**

*AquaFlow Collagen Glaucoma Drainage Device.* Among our other products is the AquaFlow Collagen Glaucoma Drainage Device, an implantable device used for the surgical treatment of glaucoma. Glaucoma is a progressive ocular disease that manifests itself through increased intraocular pressure. The increased pressure may damage the optic disc and decrease the visual field. Untreated, progressive glaucoma can cause blindness.

A surgeon implants the AquaFlow Device in the outer tissues of the eye to maintain a space that allows increased drainage of intraocular fluid so as to reduce intraocular pressure. It is made of collagen, a porous material that is compatible with human tissue and facilitates drainage of excess eye fluid. The AquaFlow Device is specifically designed for patients with open-angled glaucoma, which is the most prevalent type of glaucoma. In contrast to conventional and laser glaucoma surgeries, implantation of the AquaFlow Device does not require penetration of the anterior chamber of the eye. Instead, a small flap of the outer eye is folded back and a portion of the sclera and trabecular meshwork is removed. The surgeon places the AquaFlow Device above the remaining trabecular meshwork and Schlemm's canal and the outer flap is refolded into place. The device swells, creating a space as the eye heals. The surrounding tissue will absorb the device within six months to nine months after implantation, leaving the open space and possibly creating new fluid collector channels. The 15 to 45 minute surgical procedure to implant the AquaFlow

Device takes place under local or topical anesthesia, typically on an outpatient basis.

While STAAR's established customers for the AquaFlow device continue to implant the product, the market for the product is not expanding due to several factors, including the conservative nature of the glaucoma market, the time needed to train ophthalmic surgeons to perform the surgical procedure and the need to develop instruments or new product designs to simplify the implantation procedure. Sales of AquaFlow

devices accounted for approximately 1% of our total revenues in 2006, 1% of our total revenues in 2005, and 2% of our total revenues 2004.

### **Sources and Availability of Raw Materials**

We use a wide range of raw materials to make our products. We purchase most of our raw materials and components from external suppliers. We have relied on single sources for some of our raw materials due to regulatory constraints, cost effectiveness, availability, quality, and vendor reliability issues. Many of our components are standard parts and are available from a variety of sources, although we do not typically pursue regulatory and quality certification of multiple sources of supply.

Threats to our sources of supply for raw materials include shortages of raw materials and other market forces, natural disasters, a supplier's failure to maintain adequate quality or a recall initiated by a supplier. Even when substitute suppliers exist, 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 revenue. We try to mitigate this risk by stockpiling raw materials when practical and identifying secondary suppliers, but the risk cannot be entirely eliminated. 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, loss of our external supply source for silicone could cause us material harm. In addition, the proprietary collagen-based raw material used to manufacture our IOLs, ICLs and the AquaFlow Device is internally sole-sourced from 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.

### **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, and copyrights. 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 29, 2006, we owned approximately 104 United States and foreign patents and had approximately 42 patent applications pending.

We believe that our patents are important to our business. Of significant importance to STAAR are the patents, licenses, and technology rights surrounding our Visian ICL and Collamer material. In 1996, we were granted an exclusive royalty-bearing license to manufacture, use, and sell ICLs in the United States, Europe, Latin America, Africa, and Asia using the uniquely biocompatible Collamer material. The Collamer material is also used in certain of our IOLs. We have also acquired or applied for various patents and licenses related to our Aqua Flow Device, our phacoemulsification system, our insertion devices, and other technologies of STAAR.

Patents for individual products extend for varying periods of time according to the date a patent application is filed or a patent is granted and the term of patent protection available in the jurisdiction granting the patent. The scope of protection provided by a patent can vary significantly from country to country.

Our strategy is to develop patent portfolios for our research and development projects in order to obtain market exclusivity for our products in our major markets. Although the expiration of a patent for a product normally results in the loss of market exclusivity, we may continue to derive commercial benefits from these products. We may also be able to maintain exclusivity by patenting important improvements to the products. We routinely monitor the activities of our competitors and other third parties with respect to their use of intellectual property, including considering

whether or not to assert our patents where we believe they are being infringed.

Worldwide, all of our major products are sold under trademarks we consider to be important to our business. The scope and duration of trademark protection varies widely throughout the world. In some countries, trademark protection continues only as long as the mark is used. Other countries require registration

of trademarks and the payment of registration fees. Trademark registrations are generally for fixed but renewable terms.

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

### **Seasonality**

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 the summer months, 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.

### **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. No material part of our business, taken as a whole, is dependant upon a single or a few customers.

We maintain direct distribution to the physician or facility in the U.S., Germany and Australia. Sales efforts in Germany and Australia are primarily supported through a direct sales force. In the U.S. we sell through a network of independent manufacturers' representatives in some regions and sell through a direct sales force in other regions. We compensate the independent representatives through sales commissions and compensate direct sales staff through a combination of salary and commissions. Our independent manufacturers' representatives may represent manufacturers other than STAAR, although not in competing products. In all other countries where we do business, we sell principally through independent distributors.

We support the sales efforts of our agents, employees and distributors through the activities of our internal marketing department. Sales efforts are supplemented through the use of 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. STAAR generally keeps sufficient inventory on hand to ship product when ordered.

### **Competition**

Competition in the ophthalmic surgical product market is intense and characterized by extensive research and development and rapid technological change. Development by competitors of new or improved products, processes or technologies may make our products obsolete or less competitive. Accordingly, we must devote continued efforts and significant financial resources to enhance our existing products and to develop new products for the ophthalmic industry.

We believe our primary competitors in the development and sale of products used to surgically correct cataracts, specifically foldable IOLs and phacoemulsification machines, include Alcon Laboratories, Advanced Medical Optics,



and Bausch & Lomb. According to a 2006 Market Scope report, Alcon holds 54% of the U.S. IOL market, followed by AMO with 26% and Bausch & Lomb with 14%. We hold approximately 4% of the U.S. IOL market. Our competitors have been established longer than we have and have significantly greater resources than we have, including greater name recognition, larger sales operations, greater ability to finance research and development and proceedings for regulatory approval, and more developed regulatory compliance and quality control systems.

In the U.S. market, physicians prefer IOLs made out of acrylic. Acrylic IOLs currently account for a 62% share of the U.S. IOL market. We believe that we are positioned to compete effectively in the advanced material market segment with the Collamer IOL. We plan to introduce enhanced models of the Collamer IOL and improved injectors which we believe can strengthen our position and help reverse the decline in our overall IOL market share. Although the market for silicone IOLs, which currently account for 34% of the U.S. market, has declined in recent years, we believe they still provide an opportunity for us as we introduce improvements in silicone IOL technology and build market awareness of our Collamer IOLs and improved injection systems.

Our ICL faces significant competition in the marketplace from other products and procedures that improve or correct refractive conditions, such as corrective eyeglasses, external contact lenses, and conventional and laser refractive surgical procedures. These products and procedures are long established in the marketplace and familiar to patients in need of refractive correction. In particular, eyeglasses and external contact lenses are much cheaper and more easily obtained, because a prescription for the product is usually written following a routine eye examination in a doctor's office, without admitting the patient to a hospital or surgery center.

We believe that the following providers of laser surgical procedures are our primary competition in the marketplace for patients seeking surgery to correct refractive conditions: Advanced Medical Optics, Alcon, Bausch & Lomb, Nidek and Wave Light. All of these companies market Excimer lasers for corneal refractive surgery. Approval of custom ablation, along with the addition of wavefront technology, has increased awareness of corneal refractive surgery by patients and practitioners. Conductive Keratoplasty (CK) by Refractec competes for the hyperopic market for +.75 to +3.0 diopters. In the phakic implant market, there are only two approved phakic IOLs available in the U.S., our Visian<sup>™</sup> ICL and the AMO Verisyse. In international markets, our ICL's main competition is the Ophtec Artisan IOL, although several other phakic IOLs, manufactured by various companies, are also available.

## **Regulatory Matters**

### ***Regulatory Requirements***

We must secure and maintain regulatory approval to sell our products in the U.S. and in most foreign countries. We are also subject to various federal, state, local and foreign laws that 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 following discussion outlines the various regulatory regimes that govern our manufacturing and sale of our products.

*Regulatory Requirements in the U.S.* The federal Food, Drug & Cosmetic Act as amended by the Food and Drug Administration Modernization Act of 1997, which we refer to in this prospectus supplement as the Act authorizes the FDA to adopt 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 clearance,

require test data 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 to the FDA, and

prohibit the export of devices that do not comply with the Act unless they comply with established foreign regulations, do not conflict with foreign laws, and the FDA and the health agency of the importing country determine that export is not contrary to public health.

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, Class II or Class III. Class I devices require general controls, such as labeling and record-keeping requirements. Class II devices have performance standards in addition to general controls. Class III devices require a pre-market approval, or PMA, 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.

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 510(k) clearance is a grandfather process. As such, FDA clearance 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.

Our IOLs, ICLs, and AquaFlow Device are Class III devices. Our phacoemulsification equipment, ultrasonic cutting tips and surgical packs are Class II devices. Our lens injectors are Class I devices. We have received FDA pre-market approval for our IOLs, the ICL for the treatment of myopia, and AquaFlow Device and 510(k) clearance for our phacoemulsification equipment, lens injectors, and ultrasonic cutting tips.

As a manufacturer of medical devices, our manufacturing processes and facilities are subject to continuing review by the FDA and various state agencies to ensure compliance with quality system regulations. These agencies inspect our facilities from time to time to determine whether we are in compliance with regulations relating to manufacturing practices, validation, testing, quality control and product labeling. Our activities as a sponsor of clinical research are subject to review by the Bioresearch Monitoring Program of the FDA Office of Regulatory Affairs, known as BIMO.

*Regulatory Requirements in Foreign Countries.* The requirements for approval or clearance to market medical products in foreign countries vary widely. The requirements range from minimal requirements to requirements comparable to those established by the FDA. For example, many countries in South America have minimal regulatory requirements, while many others, such as Japan, have requirements at least as stringent as those of the FDA. Foreign governments do not always accept FDA approval as a substitute for their own approval or clearance procedures.

The member countries of the European Union require all medical products sold within their borders to carry a CE Mark. The CE Mark denotes that a medical device has been found to be in compliance with the applicable European Directives and associated guidelines concerning manufacturing and quality control, technical specifications and biological or chemical and clinical safety. We have obtained the CE Mark for all of our principal products including our ICL and TICL, IOLs (except for the Collamer three-piece IOL which we expect to receive in the second half of 2007), SonicWAVE Phacoemulsification System and our AquaFlow Device.

### ***U.S. Approval of the ICL***

The FDA Office of Device Evaluation approved the Visian ICL for the treatment of myopia on December 22, 2005. The approved models are indicated for the correction of myopia in adults with myopia ranging from -3.0 to less than

or equal to -15.0 diopters with astigmatism less than or equal to 2.5 diopters at the spectacle plane, and the reduction of myopia in adults with myopia ranging from greater than -15.0 to -20.0 diopters with astigmatism less than or equal to 2.5 diopters at the spectacle plane, in patients 21 to

45 years of age with anterior chamber depth of 3.00 mm or greater, and a stable refractive history within 0.5 diopters for one year prior to implantation.

STAAR submitted a supplemental pre-market approval application for the TICL in April 2006, and is preparing an amendment to the application in response to comments from the FDA Office of Device Evaluation. STAAR is also conducting clinical trials on the hyperopic ICL for the U.S. market.

### ***Recent Proceedings with the FDA Office of Compliance***

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 STAAR received Warning Letters, Form 483 Inspectional Observations and other correspondence from the FDA indicating that the FDA deemed STAAR's Monrovia, California facility to be violating the FDA's Quality System Regulations and Medical Device Reporting regulations, warning of possible enforcement action and suspending approval of Class III medical devices to which the violations related. STAAR responded to the FDA's observations and assertions by, among other things, comprehensively revising its quality-related operating procedures, training to implement the revised procedures, and enhancing its internal quality audit function to provide for self-regulation by verifying compliance and ensuring corrective action for noncompliance. Notwithstanding the substantial improvement in STAAR's compliance and quality, the FDA's past findings of compliance deficiencies harmed our reputation in the ophthalmic industry, affected our product sales and delayed FDA approval of the ICL. STAAR's ability to continue its U.S. business depends on the continuous improvement of its quality systems and its ability to demonstrate substantial 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's activities as a sponsor of biomedical research are subject to review by the Bioresearch Monitoring Program of the FDA Office of Regulatory Affairs (BIMO). On March 14, 2007, BIMO concluded a routine audit of STAAR's clinical trial records as a sponsor of biomedical research in connection with STAAR's Supplemental Pre-Market Approval application for the TICL. At the conclusion of the audit STAAR received eight Inspectional Observations on FDA Form 483 noting noncompliance with regulations. STAAR has submitted its response to the Inspectional Observations and expects to address the concerns raised by BIMO through voluntary corrective actions. Most of the observed instances of non-compliance took place during the 2000-2004 period. STAAR expects to show that some of these observations have already been addressed by corrective actions made in response to BIMO's observations received on December 11, 2003 in connection with STAAR's application for the ICL.

STAAR does not believe that the Inspectional Observations affect the integrity of the Toric clinical study. However, the determination of whether the Inspectional Observations affect the use of the Toric clinical study in the Toric application will be at the discretion of the FDA Office of Device Evaluation. Obtaining FDA approval of medical devices is never certain. STAAR cannot assure investors that the Office of Device Evaluation will grant approval to the TICL, or that the scope of requested TICL approval could not be limited by the FDA or the Ophthalmic Devices Panel.

### **Research and Development**

We are focused on furthering technological advancements in the ophthalmic products industry through the development of innovative ophthalmic products and materials and related surgical techniques. We maintain an active internal research and development program which includes research and development, clinical activities, and regulatory affairs and is comprised of 29 employees. In order to achieve our business objectives, we will continue the investment in research and development. Over the past year, we have principally focused, and expect to continue to

focus in 2007, our research and development efforts on the following:

Development of a Collamer Toric IOL to complement our pioneering silicone Toric IOL;

Development of a new three-piece Collamer IOL featuring an aspheric optic design;

Development of new silicone IOL models featuring aspheric optics and a squared edge configuration;

Enhancements to the injector system for our three-piece Collamer IOL to improve delivery, and development of an all new injector system for the three-piece Collamer IOL;

Development of a micro-incision injector for the one-piece Collamer IOL;

Development of a preloaded injector system for our new silicone aspheric IOLs; and

Supporting the application for U.S. approval of the Toric ICL. Research and development expenses were approximately \$7,080,000, \$5,573,000, and \$6,246,000 for our 2006, 2005 and 2004 fiscal years, respectively. STAAR expects to pay a similar amount for research and development in 2007.

### **Environmental Matters**

STAAR is 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 materially affect our capital expenditures, earnings or competitive position. We currently 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**

STAAR's only significant subsidiary is STAAR Surgical AG, a wholly owned entity incorporated in Switzerland. This subsidiary develops, manufactures and distributes products worldwide including Collamer IOLs, ICLs, TICLs and the AquaFlow Device. STAAR Surgical AG also controls 100% of Domilens GmbH, a German sales subsidiary, which distributes both STAAR products and products from other ophthalmic manufacturers.

#### ***Investigation of Fraud at Domilens GmbH***

Domilens GmbH is a wholly owned indirect subsidiary of STAAR Surgical Company based in Hamburg, Germany. It distributes ophthalmic products made by both STAAR and other manufacturers. During fiscal year 2006 Domilens reported sales of \$21.1 million.

Guenther Roepstorff founded Domilens in 1986 and operated it as an independent distributor of ophthalmic goods generally serving the market for cataract surgical products. STAAR's wholly owned Swiss subsidiary, STAAR Surgical AG, or STAAR AG, purchased 60% of Domilens in 1997, purchased another 20% in 1999, and in 2003 acquired the remaining 20%. In the 2003 transaction, Mr. Roepstorff transferred his shares to STAAR AG, and surrendered to STAAR all of his then outstanding stock options, in exchange for the cancellation of approximately \$1.03 million in indebtedness he had incurred by taking loans from Domilens without STAAR AG's approval. In the transfer agreement Mr. Roepstorff agreed that he would pay a 50% penalty on any future loans taken unilaterally and that taking any money from Domilens would be immediate cause for termination.



On January 18, 2007, Guenther Roepstorff, president of Domilens, notified STAAR he had admitted to the German Federal Ministry of Finance that without STAAR's knowledge he had diverted property of Domilens to a company under his control over a four-year period between 2001 and 2004. Mr. Roepstorff made this admission in connection with an audit conducted by the Ministry in 2006, which examined the financial records of Mr. Roepstorff, Domilens and the company to which he owned and diverted the property, Equimed GmbH (currently known as eyemaxx GmbH), covering the four-year period.

Immediately after learning these facts STAAR commenced an internal investigation of Domilens. On January 20, 2007, the Audit Committee of STAAR's Board of Directors engaged PricewaterhouseCoopers LLP ( PwC ) to conduct a forensic audit in connection with the investigation by legal counsel. The Committee subsequently engaged the law firm of Taylor Wessing, through its Hamburg office, as independent German legal counsel. The investigation included a comprehensive forensic review of the accounting records, documents and electronic records of Domilens and interviews of current employees and Mr. Roepstorff. On March 6, 2007, the Audit Committee of the Board of Directors of STAAR Surgical Company received PwC's final report.

*Key findings.* PwC investigated instances of misappropriation of corporate assets by Mr. Roepstorff between 2001 and 2006. Areas of fraudulent activity investigated by PwC included diversions of sales of IOLs and equipment to Equimed GmbH, payments to Mr. Roepstorff disguised as prepayments to suppliers and unauthorized borrowing. It is estimated that from 2001 through 2006 these activities diverted assets having a book value of approximately \$400,000 and resulted in unreported proceeds to Equimed and Mr. Roepstorff of approximately \$1,000,000.

PwC identified Mr. Roepstorff's ability to override the internal controls implemented by STAAR as a key factor in his ability to accomplish fraudulent transactions and avoid detection. In particular, they found that even after STAAR had acquired full control of Domilens and implemented further oversight he continued to run the company as his own and had a dominant presence with employees. PwC found evidence that, notwithstanding the requirements of STAAR's Code of Ethics, some Domilens employees had been aware of improper activities by Mr. Roepstorff and in some instances cooperated in documenting the activities in a manner that aided concealment. However, there is no evidence that other employees received any portion of the diverted assets or other payment for cooperation.

PwC also identified inadequate oversight of Domilens by STAAR AG and inadequate management oversight by STAAR as significant factors enabling Mr. Roepstorff to accomplish his actions. PwC has determined that a greater degree of scrutiny would have likely led to earlier detection of irregularities at Domilens.

*Impact on financial statements.* Domilens' financial results are consolidated into the audited financial statements of STAAR. STAAR has reviewed its historical financial statements, and has determined that properly accounting for past transactions in Domilens in light of the information provided by PwC's investigation did not result in a material change in STAAR's reported results of operations or reported financial condition for historical periods. STAAR has determined that the events at Domilens revealed a material weakness in its internal controls over financial reporting. Additional information on this material weakness in internal controls appears in our annual report on Form 10-K under *Item 9A. Controls and Procedures - Management Report on Internal Control over Financial Reporting.*

*Expenses related to Domilens irregularities.* It is currently estimated that the fees and reimbursable expenses of advisors incurred by STAAR in connection with the investigation will total approximately \$750,000, which will be recorded in fiscal year 2007. In addition, STAAR has reserved approximately \$700,000 against additional taxes that may be assessed for unreported sales, but will seek to reduce that amount in discussions with the German Ministry of Finance. The estimated tax liability was recorded in the fourth quarter of fiscal year 2006.

*Other Actions.* STAAR suspended all of Mr. Roepstorff's duties as president on January 19, 2007. He voluntarily resigned from his employment with Domilens on January 23, 2007. STAAR will provide all of Domilens' employees further training in their duties as employees and in STAAR's Code of Ethics. STAAR has terminated one STAAR AG employee whose responsibilities included financial oversight of Domilens. In addition, based on the advice of German counsel, the degree of individual culpability and other factors, STAAR may take other disciplinary actions, including possible termination of employees or monitoring of selected employees during a probationary period.



## Canon Staar Joint Venture

STAAR is the 50% owner of a Japan-based joint venture, Canon Staar Co., Inc., which manufactures the Preloaded Injector, a silicone or acrylic IOL preloaded into a single-use disposable injector. The co-owners of the joint venture are the Japanese optical company Canon, Inc. and its affiliated marketing company, Canon Marketing Japan Inc. Canon Marketing distributes the Preloaded Injector in Japan, and STAAR's Swiss subsidiary, STAAR AG, distributes the silicone Preloaded Injector in Europe and Australia, and on a non-exclusive basis in China and some other international markets. Canon Staar's silicone-lens-based Preloaded Injector was introduced in 2003. Canon Staar is currently seeking approval from the Japanese regulatory authorities to market in Japan the ICL, Collamer IOL and the AquaFlow Device manufactured by STAAR. The acrylic Preloaded Injector, introduced in Japan in 2006, employs a lens supplied by a Japanese ophthalmic company.

Canon Staar was created in 1988 pursuant to a Joint Venture Agreement between STAAR, Canon and Canon Marketing for the principal purpose of designing, manufacturing, and selling in Japan intraocular lenses and other ophthalmic products. The joint venture agreement provides that Canon Staar will not directly distribute its products but will distribute them worldwide through Canon, Canon Marketing, their subsidiaries, STAAR and such other distributors as the Board of Directors of Canon Staar may approve. The terms of any such distribution arrangement must be unanimously approved by the Canon Staar Board.

Several other matters require the unanimous approval of the Canon Staar Board of Directors, including appointment of key officers or directors with specific titles, acquiring or disposing of assets exceeding 20% of Canon Staar's total book value, borrowing in the principal amount of more than 20% of Canon Staar's total book value and granting a lien on any of Canon Staar's assets or contractual rights in excess of 20% of Canon Staar's total book value. STAAR is entitled to appoint, and has appointed, two of the five Canon Staar Board members. The president of Canon Staar is to be appointed, and has been appointed, by STAAR.

The Joint Venture Agreement contains numerous default provisions that give the non-defaulting party the right to acquire the defaulting party's entire interest in Canon Staar at book value. For this purpose, a party is in default under the Joint Venture Agreement (1) if the party cannot pay its debts or files for bankruptcy or similar protection, or voluntarily or involuntarily liquidates, (2) if the party defaults in its obligations under the Joint Venture Agreement and fails to cure the default within 90 days of receiving notice of default, (3) if the party undergoes a merger, acquisition or sale of substantially all of its assets, (4) if a material change occurs in management of the party, or (5) if any person or entity attempts to acquire all or a substantial portion of the party's capital stock by a tender offer or otherwise, or attempts to acquire a substantial portion of the party's business or assets.

The Joint Venture Agreement provides that the joint venture will be dissolved and its assets liquidated if an event of force majeure occurs, such as natural disaster, war, strike or governmental order, and the continuation of the event has a material adverse effect on the operations of Canon Staar. The joint venture will also be dissolved and its assets liquidated if a problem that materially affects Canon Staar or the continuation of its operations is not resolved after six months' negotiation.

In accordance with the Joint Venture Agreement, in 1988 Canon Staar and STAAR entered into a Technical Assistance and Licensing Agreement (the "TALA"), pursuant to which STAAR granted to the joint venture an irrevocable, exclusive license to STAAR's technology to make, have made, use, sell, lease or otherwise dispose of any products in Japan. The Joint Venture Agreement also gives Canon Staar a right of first refusal on any distribution of STAAR's products in Japan, contemplates a Distribution Agreement to cover the resulting arrangement, gives Canon Staar the right to purchase from STAAR manufacturing equipment and tooling necessary to manufacture intraocular lenses, and contemplates a Supply Agreement to cover the resulting arrangement. The Joint Venture Agreement also

contemplates that the relevant parties will enter into a Company's Name License Agreement giving Canon Staar a license to use the founding parties' names. To date, the parties have not entered into any such Distribution Agreement, Supply Agreement or Company's Name License Agreement.

Under the TALA, STAAR granted Canon Staar a royalty free, fully paid-up, irrevocable, exclusive license to make, have made, use, sell, lease or otherwise dispose of any products in Japan using or incorporating STAAR's Licensed Technology. Licensed Technology means all intellectual property relating to intraocular lenses, surgical packs, phacoemulsification machines, ophthalmic solutions, other pharmaceuticals and medical equipment, owned or controlled by STAAR as of the date of the TALA or thereafter. Under the TALA, STAAR also granted Canon Staar a royalty-free, fully paid-up, irrevocable, non-exclusive license to use, sell, lease or otherwise dispose of any products in the rest of the world using or incorporating STAAR's Licensed Technology. The TALA also provides that STAAR will provide the Licensed Technology in written or other tangible form to enable Canon Staar to make, sell and service products and provide training and consulting services in connection with the manufacture of products. In consideration of the licenses and rights granted by STAAR under the TALA, Canon Staar paid STAAR \$3 million. The TALA continues in effect until such time as the parties agree to terminate it.

In 2001, the joint venture parties, including Canon Staar, entered into a Settlement Agreement under which they reconfirmed the Joint Venture Agreement and the TALA and STAAR agreed promptly to commence the transfer to Canon Staar under the TALA of all of its new or advanced technology, including technology related to collamer IOL, glaucoma wicks and ICL. In the Settlement Agreement STAAR also granted Canon Staar a royalty free, fully paid-up, perpetual, exclusive license to use STAAR's Licensed Technology to make and have made any products in China and sell such products in Japan and China (subject to STAAR's existing licenses and the existing rights of third parties). The Settlement Agreement also provided that STAAR would enter into a raw material supply agreement covering the supply of raw materials to Canon Staar and would continue to supply raw materials under existing arrangements until execution of the supply agreement. The Settlement Agreement further provided that Canon Marketing would enter into a distribution agreement with Canon Staar governing Canon Marketing's status as Canon Staar's exclusive distributor in Japan. The distribution agreement would provide that the selling prices by Canon Staar of its products to Canon Marketing will be in the range of 50% to 70% of the sales price of the products from Canon Marketing to its end customers through its own sales channel, with the pricing to be reviewed annually and subject to unanimous approval of the Canon Staar Board. The Settlement Agreement provides that until the distribution agreement is executed the Canon Staar will sell its products to Canon Marketing at its then current prices, provided the prices are within the 50-70% range. The parties also settled certain patent disputes. To date, the parties have not entered into the supply agreement or distribution agreement.

Canon Staar has a single class of capital stock, of which STAAR owns 50%. Accordingly, STAAR is entitled to 50% of any dividends or distributions by Canon Staar and 50% of the proceeds of any liquidation.

The foregoing description of the joint venture agreement, TALA and Settlement Agreement is qualified in its entirety by the full text of such agreements, which have been filed as exhibits or incorporated by reference to this report. The joint venture agreement, TALA and Settlement Agreement are governed by the laws of Japan, and contain provisions that may be open to different interpretations. Accordingly, these agreements may be interpreted in a manner that may be materially adverse to the interests of STAAR, and any description of these agreements is subject to uncertainty. See *Risk Factors* We have licensed our technology to our joint venture company, which could cause our joint venture company to become a competitor ; and *Risk Factors* Our interest in Canon Staar may be acquired for book value on the occurrence of specified events, including a change in control of STAAR.

## Employees

As of March 23, 2007, we employed approximately 284 persons.

**Contractual Obligations**

The following table represents our known contractual obligations as of December 29, 2006 (in thousands):

Contractual Obligations	Total	Payments Due by Period			
		Less than 1 year	1-3 Years	3-5 Years	More than 5 years
Notes payable	\$ 1,802	1,802			
Capital lease obligations	1,720	647	1,073		
Operating lease obligations	4,254	1,344	2,637	273	
Purchase obligations(1)	1,289	600	689		
Other current-term liabilities	927	927			
Open purchase orders	1,278	1,278			
Total	\$ 11,270	6,598	4,399	273	

On March 21, 2007 STAAR entered into a Promissory Note with Broadwood Partners, LP evidencing \$4 million of indebtedness, which becomes due and payable on March 21, 2010, and 10% interest per annum payable on a quarterly basis. The Promissory Note is not included in the table of contractual obligations above because it was not outstanding on December 29, 2006. The Promissory Note provides the Broadwood will have a right to participate in any equity offering of STAAR on a pro rata basis (based on Broadwood's percentage ownership of STAAR) until the later of March 21, 2008 and the date on which the Promissory Note is no longer outstanding. In connection with the issuance of the Promissory Note, STAAR issued certain warrants to Broadwood and granted resale registration rights with respect to the shares underlying warrants.

*Contractual Restrictions under our Credit Arrangements*

Among other limitations they may place on our operations, our credit arrangements include covenants that restrict intercompany financial transactions. A change in control of STAAR may also result in a default or right of termination by the lender under our credit arrangements.

The Master Credit Agreement between our subsidiary, STAAR Surgical AG, and UBS AG prohibits STAAR Surgical AG from distributing earnings to STAAR without the consent of UBS, limits receivables from STAAR to approximately \$1 million and requires STAAR AG to maintain minimum equity of \$12 million. The Master Credit Agreement also provides that UBS will have a right to terminate the agreement if STAAR Surgical AG has a change of ownership or controlling interest that UBS deems material.

The Credit and Security Agreement between STAAR and Wells Fargo Bank prohibits STAAR from incurring indebtedness to its subsidiaries or investing in its subsidiaries without the consent of the Bank. The Credit and Security Agreement also provides that a change of control of STAAR will constitute a default of the agreement. A change of control under the agreement includes the acquisition of 15% or more of STAAR's capital stock by any person or group, a change in composition of the Board of Directors over a two-year period that results in the directors in place at the beginning of the period no longer constituting a majority, or David Bailey's ceasing to actively manage STAAR. On March 21, 2007, Wells Fargo Bank waived a covenant prohibiting STAAR from incurring of additional indebtedness, which permitted STAAR to enter into the Promissory Note with Broadwood Partners, LP on that date.

STAAR may terminate its credit agreements with UBS and Wells Fargo at any time, but may incur substantial prepayment penalties as a result.

**Off-Balance Sheet Arrangements**

We do not have any off-balance sheet arrangements, as that term is defined in the rules of the SEC, that have or are reasonably likely to have a current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources that are material to investors.

**Item 9.01 Financial Statements and Exhibits.**

c) Exhibits.

<b>Exhibit No.</b>	<b>Description</b>
1.01	Underwriting Agreement
5.1	Opinion regarding legality of securities
23.1	Consent of Charles Kaufman, Esq. (including in Exhibit 5.1).



**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

STAAR Surgical Company

April 25, 2007

By: /s/ Deborah Andrews

Name: Deborah Andrews

Title: Vice President and Chief Financial  
Officer

Exhibit Index

<b>Exhibit No.</b>	<b>Description</b>
1.01	Underwriting Agreement
5.1	Opinion regarding legality of securities
23.1	Consent of Charles Kaufman, Esq. (included in Exhibit 5.1).