STAAR SURGICAL CO
Form 424B3
September 27, 2006

Table of Contents

PROSPECTUS SUPPLEMENT to
Prospectus Dated January 14, 2004

This filing is made pursuant to
Rule 424(b)(3) under the
Securities Act of 1933 in connection
with Registration No. 333-111140

STAAR Surgical Company
120,000 Shares
Common Stock
($0.01 Par Value)

This is an offering of common stock of STAAR Surgical Company, or STAAR. All of the shares are being offered by the selling stockholder listed in the section of this prospectus entitled Selling Stockholder. The selling stockholder will use the proceeds from the sale of his 120,000 shares to repay his pre-existing indebtedness to STAAR.

Our common stock trades on the Nasdaq National Market under the symbol STAA. On September 26, 2006, the closing sales price for our common stock on the Nasdaq National Market was $7.55 per share.

This prospectus supplement supplements the prospectus dated January 14, 2004 and should be read in conjunction with the prospectus.

Investment in our common stock involves a high degree of risk. Please carefully consider the Risk Factors beginning on page 4 of this prospectus.

Neither the Securities and Exchange Commission, nor any state securities commission, has approved or disapproved of these securities or determined if this prospectus is truthful or complete. **Any representation to the contrary is a criminal offense.**

The date of this prospectus supplement is September 26, 2006.

TABLE OF CONTENTS

You should rely only on the information contained in the prospectus, in this prospectus supplement, or to which the prospectus and this prospectus supplement specifically refer you. We have not authorized anyone else to provide you with different information. This document may be used only where it is legal to sell these securities. The information in this prospectus supplement may only be accurate on the date of this prospectus supplement.

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

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

Statements in this prospectus supplement and in the prospectus that are not statements of historical fact are forward-looking statements. These statements relate to our future plans, objectives, expectations and intentions.

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

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

Table of Contents

PROSPECTUS SUMMARY

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

Cataract Surgery

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

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

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

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

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

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

Refractive Surgery

Manufacturing and selling lenses for refractive surgery is an increasingly important source of revenue for STAAR. We have used our proprietary biocompatible Collamer material to develop and manufacture implantable Collamer lenses, or ICLs. STAAR s VISIAN™ ICL and VISIAN™ Toric ICL, or TICL. treat refractive disorders such as myopia (near-sightedness), hyperopia (far-sightedness) and astigmatism. These disorders of vision affect a large proportion of the population. Unlike the IOL, which replaces a cataract patient s cloudy lens, these products are designed to work with the patient s natural lens to correct refractive disorders. The surgeon implants the foldable Visian lens through a tiny incision, generally under local anesthesia. STAAR began selling the Visian ICL outside the U.S. in 1996 and the Visian TICL in 2002. The U.S. Food and Drug Administration, or FDA, approved the Visian ICL for the treatment of myopia in the U.S. in December 2006, and the Visian family of refractive implants is sold in approximately 42 countries. The Company s goal is to establish the position of the ICL and

Table of Contents

TICL throughout the world as an accepted choice for the surgical treatment of refractive errors, alongside such better known treatment as LASIK.

Other products

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

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

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

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

The Offering

The selling stockholder listed in the section of this prospectus supplement entitled Selling Stockholder may offer and sell up to 120,000 shares of our common stock.

Under the prospectus, the selling stockholder may sell his shares of common stock in the open market at prevailing market prices or in private transactions at negotiated prices. He may sell the shares directly, or may sell them through underwriters, brokers or dealers. Underwriters, brokers or dealers may receive discounts, concessions or commissions from the selling stockholder or from the purchaser, and this compensation might be in excess of the compensation customary in the type of transaction involved. See the section of this prospectus supplement entitled Plan of Distribution.

Table of Contents

RISK FACTORS

An investment in our common stock involves a high degree of risk. In addition to the other information contained in this prospectus, you should carefully consider the following risks and uncertainties before purchasing our common stock. If any of these risks or uncertainties were to occur, our business, financial condition and operating results could suffer serious harm. In that case, the trading price of our common stock could decline and you could lose all or part of your investment.

Risks Related to Our Business

We have a history of losses and anticipate future losses.

We have reported losses in each of the last four fiscal years and have an accumulated deficit of $78.2 million as of June 30, 2006. There can be no assurance that we will report net income in any future period.

We have only limited working capital.

We believe that our current sources of working capital are sufficient to satisfy our anticipated working capital requirements for fiscal 2006. However, the sufficiency of our working capital largely depends on a successful launch of the ICL and reversing the declining trends in our cataract business. If acceptance of the ICL is slower than anticipated and we are unable to reverse the declines in our cataract business, our working capital may be insufficient for future years and we may have to consider alternative sources of funding. We can provide no assurance as to the availability of such funding or the terms upon which it might be available.

We have limited access to credit and could default on the terms of our loan agreement.

As of September 26, 2006, the Company had approximately $3.2 million available for borrowing under U.S. and International bank credit facilities and lease lines of credit. The credit facilities are subject to various financial covenants and if our losses continue, we risk defaulting on the terms of our credit facilities. Our limited borrowing capacity could cause a shortfall in working capital or prevent us from making expenditures to expand or enhance our business. A default on any of our loan agreements could cause our long term obligations to be accelerated, make further borrowing difficult and jeopardize our ability to continue operations.

We have only limited access to financing.

Because of our history of losses, our ability to obtain adequate financing on satisfactory terms or at all is limited. On May 17, 2006, our stockholders approved an increase on our authorized shares of common stock from 30 million shares to 60 million shares, which could enable STAAR to obtain financing in the public equity markets. However, 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 shareholders could experience substantial dilution. An inability to secure additional financing

could limit our ability to expand our business. If we fail to achieve profitability and cannot secure adequate funding, our ability to continue operations would be in jeopardy.

Recent 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 s most recent inspection of STAAR s Monrovia, California facility, 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 the Company 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.

The FDA s findings of compliance deficiencies during the preceding two years have harmed our reputation in the ophthalmic industry and 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 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 these efforts will always be successful, and any failure to demonstrate substantial compliance with these regulations can result in enforcement actions that terminate, suspend or severely restrict our ability to continue manufacturing and selling medical devices.

Our success depends on the successful marketing of the ICL in the United States market.

The FDA approved the sale of the ICL for treatment of myopia on December 22, 2005. The ICL will not reach its full sales potential unless we successfully plan and execute its launch and marketing in the United States. This presents new challenges to our sales and marketing staff and to our independent manufacturers representatives. In countries where the ICL has been approved to date, our sales have grown steadily, but slowly. In the United States in particular, 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. As a result, we expect to make extensive use of advertising and promotion targeted to potential patients through providers, and to carefully manage the introduction of the ICL. Final training of surgeons in the U.S. will be conducted by a finite number of proctors on our staff. Our resources are limited and we cannot predict whether the particular marketing, advertising and promotion strategies we pursue will be as successful as we intend. If we do not successfully market the ICL in the United States, we will not achieve our planned profitability and growth.

Table of Contents

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

STAAR pioneered the foldable IOL for use in cataract surgery, and 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 gradually taken a larger 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 an effort to maintain our competitive position we have introduced IOLs made of a biocompatible lens material, Collamer, and more recently a three-piece silicone IOL preloaded into a single-use disposable injector which is sold internationally. Despite the introduction of these products, our overall cataract business has continued to decline in recent periods.

We face stronger competition from multifocal and accommodating lenses because of a change in Medicare reimbursement rules.

The Centers for Medicare and Medicaid Services have changed the reimbursement policy applicable to cataract surgery by permitting Medicare-covered cataract patients to receive higher-cost multifocal IOLs by paying only the additional cost of the lens and surgical procedure while still receiving reimbursement for the basic cost of cataract surgery and a monofocal IOL. This has made the more costly cataract lenses that claim to reduce or eliminate the need for spectacles for close-up vision more accessible financially for older patients with active lifestyles. STAAR does not sell a multifocal or accommodating lens design and cannot participate in this market. Moreover, surgeons receive significant additional fees when they implant multifocal or accommodating lenses. Accordingly, the time and attention of many surgeons in our U.S. target market who might otherwise have been interested in adopting the ICL or our advanced cataract products have instead been absorbed with multifocal and accommodating cataract products. Competition from multifocal lenses under the new Medicare reimbursement rules has taken business from STAAR s domestic cataract business, and we expect it to continue to do so, but the full impact of this trend cannot be estimated at this time.

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

In many countries where STAAR sells its products, ophthalmologists and other doctors 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 can affect sales of our products. For example, in the first six months of 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. 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.

Table of Contents

Because state-sponsored healthcare systems, health maintenance organizations and insurance reimbursement usually do not cover refractive surgery, job actions by doctors are unlikely to affect ICL sales.

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. We have been relying on the independent representatives to introduce our new products like Collamer IOLs, Toric IOLs and the AquaFlow Device, and we are relying on them, in part, to help introduce 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. Despite all efforts to achieve the highest level of quality control and advance testing, 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 a 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. During 2004, we initiated several voluntary recalls of STAAR-manufactured product 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. While the majority of the direct costs associated with the recalls have not been material, we believe recalls have harmed our reputation and adversely affected our product sales, although the

Table of Contents

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 some 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. As part of our risk management policy, we have obtained third-party product liability insurance coverage. In recent periods this insurance 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

Table of Contents

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 30, 2005, sales from international operations were 64% of 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 United States 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 United States 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. Fluctuations in the value of the United States dollar against other currencies have not had a material adverse effect on our operating margins and profitability in the past.

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 United States 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.

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. Although we believe we could find alternate supplies for any of these components, the loss or interruption of any of these suppliers could increase costs, reducing our sale 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 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.

Table of Contents

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

Our manufacturing, research and development practices involve the controlled 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. Although we believe that our safety and environmental procedures for handling and disposing of these materials comply with legally prescribed standards, 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.

STAAR and its Chief Executive Officer have been parties to a class action lawsuit in the United States District Court for the Central District of California, which generally alleged that the defendants, STAAR Surgical Company and its Chief Executive Officer, violated Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, as amended, and Rule 10b-5 promulgated thereunder, by issuing false and misleading statements regarding the prospects for FDA approval of STAAR s Visian ICL, thereby artificially inflating the price of the Company s Common Stock. The plaintiffs sought to recover compensatory damages, including interest. On September 25, 2006, the Court held a hearing to consider granting final approval to settlement of the class action lawsuit. At the conclusion of the hearing, the Court found that the settlement previously negotiated to resolve the lawsuit was fair, just, reasonable and adequate and approved the settlement in all respects. The Court finally certified for settlement purposes a class comprised of purchasers of STAAR s securities between October 6, 2003 and January 5, 2004. Under the terms of the settlement, in exchange for dismissal of the lawsuit and a general release of claims and without admission of liability, STAAR previously caused payment of $3,700,000 to be made, all but $100,000 of which was paid by STAAR s insurance carrier. STAAR s total expenditure in connection with the lawsuit will not exceed the $500,000 retention amount under its insurance policy, which was fully accrued as of December 30, 2005.

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

Table of Contents

to identify, attract, train and motivate other highly skilled personnel. Failure to do so may adversely affect future results.

We have licensed our technology to our joint venture company and have granted certain rights to the partners that could be exercised in the event of a change in control of the Company.

We have granted to the Canon Staar joint venture, an irrevocable, exclusive license to make and sell products using our technology in Japan. We have also granted the joint venture an irrevocable, exclusive license to make products using our technology in China and to sell in China and Japan the products made in China. In addition, we have granted Canon Staar an irrevocable, non-exclusive license to sell products using our technology in the rest of the world. Subject to the unanimous approval of the Board of Directors of the joint venture, such licenses may allow the Canon Staar joint venture to sell products in the rest of the world directly or through distributors.

If a party to the Canon Staar joint venture undergoes a merger, sale of substantially all of its assets or changes its management, any of the other joint venture partners has the right to acquire that party s interest in the joint venture at book value. The terms of the principal agreements governing the joint venture are described in our Annual Report on Form 10-K under the caption 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, resulting in significant changes in our reported results of operation or financial condition.

We are subject to international taxation 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. STAAR engages in dialogue with tax authorities in some of the countries where it operates to mitigate this risk, but it cannot be entirely eliminated. 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. In particular, 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. Although we carry insurance for property damage and business interruption, we do not carry insurance or financial reserves 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 increasingly 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 Company 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 substantially superior product, or if we announce a new product of our own. Similarly, 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 of time; 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 10.9% of our sales on research and development during the year ended December 30, 2005, and we expect to spend approximately 10% 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

Table of Contents

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. It is possible that few or none of the products currently under development will become commercially successful.

Failure of users of our products to obtain adequate reimbursement from third-party payors could limit market acceptance of our products, which could affect our sales and profits.

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. These third-party payors have recently been trying to contain costs by restricting the types of procedures they reimburse to those viewed as most cost-effective and capping or reducing reimbursement rates. These polices could adversely affect sales and prices of our products. Physicians, hospitals and other health care providers may be reluctant to purchase our products if third-party payors do not adequately reimburse them for the cost of our products and the use of our surgical equipment. For example:

Major third-party payors for hospital services, including government insurance plans, Medicare, Medicaid and private health care insurers, have substantially revised their payment methodologies during the last few years, resulting in stricter standards for reimbursement of hospital and outpatient charges for some medical procedures, including cataract procedures and IOLs;

Numerous legislative proposals have been considered that, if enacted, would result in major reforms in the United States health care system, which could have an adverse effect on our business;

Our competitors may reduce the prices of their products, which could result in third-party payors favoring our competitors;

There are proposed and existing laws and regulations governing maximum product prices and the profitability of companies in the health care industry; and

There have been recent initiatives by third-party payors to challenge the prices charged for medical products. Reductions in the prices for our products in response to these trends could reduce our sales. Moreover, our products may not be covered in the future by third-party payors, which would also reduce our sales.

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

Government regulations and agency oversight apply to every aspect of our business, including testing, manufacturing, safety and environmental controls, efficacy, labeling, advertising, promotion, record keeping, the sale and distribution of products and samples. We are

Table of Contents

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 United States, we must obtain approval from the FDA for each product that we market. Competing in the ophthalmic products industry requires us to continuously introduce new or improved products and processes, 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 in the United States are subject to periodic inspection by the FDA. 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.

Products distributed outside of the United States are also subject to government regulation, which may be equally or more demanding. 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 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.

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

We have numerous patents and pending patent applications. We rely on a combination of 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. Furthermore, we cannot be certain that any pending patent application held by us will result in an issued patent or that if patents are issued to us, the patents will 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 not fully resolved.

Any litigation or claims against us, whether or not successful, could result in substantial costs and harm our reputation. In addition, intellectual property litigation or claims could force us to do one or more of the following: to cease selling or using any of our products that incorporate the challenged intellectual property, which would adversely affect our sales; to negotiate a license from the holder of the intellectual property right alleged to have been

Table of Contents

infringed, which license may not be available on reasonable terms, if at all; or to 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 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 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 charge a lower price in order to maintain sales of our products, which could make these products 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 Certificate of Incorporation 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 would be in the interest of a significant number of our stockholders or if such a change in control would provide our stockholders with a substantial premium for their shares over the then-prevailing market price for the common stock.

Our bylaws contain other provisions that could have an anti-takeover effect, including the following:

stockholders have limited ability to remove directors;

stockholders cannot act by written consent;

stockholders cannot call a special meeting of stockholders; 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

Table of Contents

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.

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.

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

Our stock price has fluctuated widely, ranging from $4.87 to $9.53 during the twelve months ending September 26, 2006. Our stock price could continue to experience significant fluctuations 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.

USE OF PROCEEDS

The 120,000 shares of common stock offered under the prospectus are offered by the selling shareholder. The selling shareholder will apply the net proceeds of the offering to repay his pre-existing indebtedness to STAAR. STAAR intends to use any of the net proceeds it receives for general corporate purposes, including working capital. Until applied to that use, STAAR intends to invest the net proceeds in investment grade, interest-bearing securities.

Table of Contents

SELLING STOCKHOLDER

The following table lists the number of shares of our common stock registered for sale by the selling stockholder under the prospectus. It also shows the total number of shares of common stock owned by him before and after the offering, and the percentage of our total outstanding shares represented by these amounts. The table reflects our assumption that the selling stockholder will sell all of the common stock being offered by the prospectus for his account.

The selling stockholder, Dr. Peter Utrata, was a member of our board of directors until he resigned on January 28, 2003. He has had no other relationship with our company other than as stockholder and director during the last three fiscal years. The selling stockholder purchased the shares offered in the prospectus from us in transactions that were exempt from registration under the Securities Act of 1933 under Section 4(2) of the Act or Rule 506 of Regulation D promulgated under the Act.

The selling stockholder is indebted to STAAR under two promissory notes, one dated June 16, 1999 in the original principal amount of $1,258,000, and another dated June 15, 2004 in the original principal amount of $272,500. The 1999 Note was used pay the purchase price of the 120,000 shares offered by the prospectus, and the selling stockholder s obligations under both notes are secured by a pledge of those shares. When the 1999 note was not paid after its maturity date, the selling stockholder and STAAR entered into a Forbearance Agreement dated July 22, 2004, whereby the Company agreed to extend the time for repayment of that note in consideration of a cash payment of $150,000 against accrued interest and the selling shareholder s reaffirmation of his obligations. As of September 22, 2006, both of the notes remained unpaid after their maturity dates and after the expiration of the forbearance period, and they had accrued a total of $410,218.28 in unpaid interest. The selling stockholder also claimed that STAAR owed him unpaid obligations that he was entitled to offset against the indebtedness under the notes.

On September 22, 2006, STAAR and the selling stockholder entered into an Agreement of Settlement and Mutual Release, under which the parties mutually agreed to release their claims against each other. Under the agreement STAAR will discharge the selling stockholder s total indebtedness of $1,940,718.28 under the notes in consideration of a cash payment of $175,000 and the selling stockholders agreeing to cause the shares to be sold with the net proceeds of the sale to be delivered to STAAR. Since January 23, 2004 the shares have been held in a controlled account that affords STAAR the right to direct the sale of the shares.

The table is based on information provided by the selling stockholder, and does not necessarily indicate beneficial ownership for any other purpose. The number of shares of common stock beneficially owned by the selling stockholder is determined in accordance with the rules of the SEC. The term selling stockholder includes the stockholder listed below and his transferees, assignees, pledgees, donees or other successors. The percent of beneficial ownership for the selling stockholder is based on 25,529,493 shares of common stock outstanding as of September 26, 2006.

Table of Contents

Name of Selling Stockholder	Number of Shares of Common Stock Beneficially Owned Prior to Offering (1)	Percent of Outstanding Shares of Common Stock Beneficially Owned Prior to Offering (1)	Number of Shares of Common Stock to be Offered Pursuant to this Prospectus	Number of Shares of Common Stock Beneficially Owned After the Offering (2)	Percent of Outstanding Shares of Common Stock Beneficially Owned After the Offering (2)
Dr. Peter J. Utrata(3) 303 E. Town Street Columbus, OH 43215	160,000	*%	120,000	40,000	*%

* Represents less than 1% of the outstanding shares.

(1) The number and percentage of shares beneficially owned is determined in accordance with Rule 13d-3 of the Securities Exchange Act of 1934, as amended, and the information is not necessarily indicative of beneficial ownership for any other purpose. Under Rule 13d-3, the number of shares beneficially owned includes

any shares as to which a person has sole or shared voting power or investment power. Shares which a person has the right to acquire within 60 days of the date of this prospectus supplement are included in the shares owned by that person and are treated as outstanding for purposes of calculating the ownership percentage of that person, but not for any other person.

(2) Assumes that all shares being offered by the selling stockholder under the prospectus are sold, that the selling stockholder acquires no additional shares of common stock before the completion of this offering, and that the selling stockholder disposes of no shares of common stock other than those

offered under the prospectus.

(3) Includes options to purchase up to 40,000 shares of STAAR Surgical Company common stock.

PLAN OF DISTRIBUTION

The selling stockholder and his successors, including his transferees, pledgees or donees, may sell the shares covered by the prospectus from time to time for his own account. The shares have been pledged to STAAR as security for indebtedness of the selling stockholder, and STAAR may direct all or part of the shares to be sold. The selling stockholder may sell his shares on the Nasdaq National Market or other exchanges, in the over-the-counter market or in privately negotiated transactions. He may sell his shares directly or through underwriters, broker-dealers or agents, who may receive compensation in the form of discounts, concessions, or commissions from the selling stockholder or from the purchasers of the shares. The compensation received by a particular underwriter, broker, dealer or agent might exceed customary commissions.

The shares of common stock may be sold in one or more transactions at fixed prices, at prevailing market prices at the time of sale, at prices related to the prevailing market prices, at varying prices determined at the time of sale, or at negotiated prices.

The selling stockholder may sell his shares through any of the following methods or any combination of these methods:

purchases by a broker or dealer as a principal and resale by that broker or dealer for its own account under the prospectus;

ordinary brokerage transactions and transactions in which the broker solicits purchasers, which may include long or short sales made after the effectiveness of

Table of Contents

the registration statement of which this prospectus supplement and the prospectus is a part;

cross trades or block trades in which the broker or dealer engaged to make the sale will attempt to sell the securities as an agent, but may position and resell a portion of the block as a principal to facilitate the transaction;

through the writing of options;

in other ways not involving market makers or established trading markets, including direct sales to purchasers or sales made through agents;

any combination of the above transactions; or

any other lawful method.

In addition, any securities covered by the prospectus that qualify for sale in compliance with Rule 144 promulgated under the Securities Act of 1933 may be sold under Rule 144 rather than under the prospectus.

The selling stockholder may enter into hedging transactions with broker-dealers in connection with distributions of the shares or otherwise. In these transactions, broker-dealers may engage in short sales of common stock in the course of hedging the positions they assume with the selling stockholder.

The selling stockholder also may sell shares short and redeliver the shares to close out such short positions. He may enter into options or other transactions with broker-dealers that require the delivery to the broker-dealer of the shares. The broker-dealer may then resell or otherwise transfer the shares covered by the prospectus (which may be amended or supplemented to reflect the transaction). The selling stockholder also may loan or pledge the shares to a broker-dealer or another financial institution. If the selling stockholder defaults on the loan or the obligation secured by the pledge, the broker-dealer or institution may sell the shares so loaned or pledged under the prospectus (which may be amended or supplemented to reflect the transaction).

Broker-dealers or agents may receive compensation in the form of commissions, discounts or concessions from the selling stockholder or his successors. Broker-dealers or agents may also receive compensation from the purchasers for whom they act as agents or to whom they sell as principals, or both. Compensation received by a particular broker-dealer might be in excess of customary commissions and will be in amounts to be negotiated in connection with the sale.

Broker-dealers or agents and any other participating broker-dealers or the selling stockholder or his successors may be deemed to be underwriters within the meaning of Section 2(11) of the Securities Act in connection with sales of shares. Accordingly, any such commission, discount or concession received by them and any profit on the resale of the shares

Table of Contents

purchased by them may be deemed to be underwriting discounts or commissions under the Securities Act.

The selling stockholder has advised us that he has not entered into any agreements, understandings or arrangements with any underwriters or broker-dealers regarding the sale of his securities and that there is no underwriter or coordinating broker acting in connection with the proposed sale of shares by the selling stockholder.

We have agreed to pay the expenses of registering the shares under the Securities Act, including registration and filing fees, printing expenses, administrative expenses and certain legal and accounting fees. The selling stockholder will bear all discounts, commissions or other amounts payable to underwriters, dealers or agents as well as fees and disbursements for legal counsel retained by the selling stockholder.

The selling stockholder may agree to indemnify any agent, dealer or broker-dealer that participates in transactions involving sales of shares against liabilities, including liabilities arising under the Securities Act.

Because the selling stockholder may be deemed to be an underwriter within the meaning of Section 2(11) of the Securities Act, he will be subject to the prospectus delivery requirements of the Securities Act. If we are required to supplement this prospectus or post-effectively amend the registration statement to disclose a specific plan of distribution of the selling stockholder, the supplement or amendment will describe the particulars of the plan of distribution, including the shares of common stock, purchase price and names of any agent, broker, dealer, or underwriter or arrangements relating to any such an entity or applicable commissions.

Under applicable rules and regulations under the Securities Exchange Act of 1934, as amended, no person engaged in the distribution of the shares may simultaneously engage in market making activities with respect to our common stock for a restricted period before the commencement of the distribution. In addition, the selling stockholder will be subject to applicable provisions of the Securities Exchange Act and the associated rules and regulations under the Securities Exchange Act, including Regulation M, the provisions of which may limit the timing of purchases and sales of the shares by the selling stockholder.

We will make copies of this prospectus supplement and the prospectus available to the selling stockholder and have informed the selling stockholder of the need to deliver copies of this prospectus to purchasers at or before the time of any sale of the shares.

Our common stock is traded on the Nasdaq National Market under the symbol STAA. The transfer agent for our shares of common stock is American Stock Transfer & Trust Co., 59 Maiden Lane, New York, NY 10038.

Table of Contents

LEGAL MATTERS

The validity of the issuance of the shares of common stock in this offering has been passed upon for us by Sheppard, Mullin, Richter & Hampton LLP, Los Angeles, California.

EXPERTS

The consolidated financial statements and schedule and management s report on the effectiveness of internal control over financial reporting incorporated by reference in the Prospectus have been audited by BDO Seidman, LLP, an independent registered public accounting firm, to the extent and for the periods set forth in their reports incorporated herein by reference, and are incorporated herein in reliance upon such reports given upon the authority of that firm as experts in auditing and accounting.

WHERE YOU CAN FIND MORE INFORMATION

Because we are subject to the informational requirements of the Securities Exchange Act, we file reports, proxy statements and other information with the SEC. You may read and copy these reports, proxy statements and other information at the public reference room maintained by the SEC at the following address:

Public Reference Room 450 Fifth Street, N.W. Washington, D.C. 20549

You may obtain information on the operation of the public reference room by calling the SEC at (800) SEC-0330. In addition, we are required to file electronic versions of those materials with the SEC through the SEC s EDGAR system. The SEC maintains a web site at http://www.sec.gov, which contains reports, proxy statements and other information regarding registrants that file electronically with the SEC.

We have filed with the SEC a registration statement on Form S-3 under the Securities Act with respect to the securities offered with the prospectus. This prospectus supplement and the prospectus do not contain all of the information in the registration statement, parts of which we have omitted, as allowed under the rules and regulations of the SEC. You should refer to the registration statement for further information with respect to us and our securities. Statements contained in this prospectus supplement and the prospectus as to the contents of any contract or other document are not necessarily complete and, in each instance, we refer you to the copy of each contract or document filed as an exhibit to the registration statement. Copies of the registration statement, including exhibits, may be inspected without charge at the SEC s principal office in Washington, D.C., and you may obtain copies from that office upon payment of the fees prescribed by the SEC.

We will furnish without charge to each person to whom a copy of the prospectus is delivered, upon written or oral request, a copy of the information that has been incorporated by reference the prospectus (except exhibits, unless they are specifically incorporated by reference into the prospectus). You should direct any requests for copies to: Investor Relations, STAAR Surgical Company, 1911 Walker Avenue, Monrovia, California 91016, telephone number (626) 303-7902.

Table of Contents

INFORMATION INCORPORATED BY REFERENCE

The Securities and Exchange Commission, or SEC, allows us to incorporate by reference into the prospectus the information that we file with the SEC. This means that we can disclose important information by referring the reader to those SEC filings. The information incorporated by reference is considered to be part of the prospectus, and later information we file with the SEC will update and supersede this information. We incorporate by reference the documents listed below and any future filings made with the SEC under Section 13(a), 13(c), 14, or 15(d) of the Securities Exchange Act prior to the termination of the offering:

our Annual Report on Form 10-K for our fiscal year ended December 30, 2005;

our Proxy Statement for the Annual Meeting of Stockholders held on May 17, 2006, filed with the SEC on April 14, 2006;

our Quarterly Report on Form 10-Q for the period ended June 30, 2006;

our Current Report on Form 8-K filed on August 21, 2006;

our Current Report on Form 8-K, Items 1.01 and 8.01, filed on September 26, 2006; and

the description of our common stock contained in Amendment No. 1 to our registration statement on Form 8-A/A filed with the SEC on April 18, 2003, including any amendment or report filed for the purpose of updating this description.

You may obtain copies of those documents from us, free of cost, by contacting us at the address or telephone number provided in Where You Can Find More Information immediately above.