STAAR SURGICAL CO
Form 424B3
May 20, 2005

PROSPECTUS

This filing is made pursuant to Rule 424(b)(3) under the Securities Act of 1933 in connection with Registration No. 333-124022

STAAR Surgical Company

4,100,000 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 stockholders listed in the section of this prospectus entitled Selling Stockholders. We will not receive any of the proceeds from the sale of the 4,100,000 shares being offered by the selling stockholders.

Our common stock trades on the Nasdaq National Market under the symbol STAA. On May 19, 2005, the closing sales price for our common stock on the Nasdaq National Market was $4.00 per share.

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 is May 19, 2005.

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You should rely only on the information contained in this prospectus or to which we have referred 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 may only be accurate on the date of this prospectus.

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

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

Statements in this 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 generally identify these 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, and in our other reports we file with the Securities and Exchange Commission. The forward-looking statements in this prospectus speak only as of the date of this prospectus, and you should not rely on these statements without also considering the risks and uncertainties associated with these statements and our business.

PROSPECTUS SUMMARY

STAAR Surgical Company

STAAR develops, manufactures and distributes worldwide products used by ophthalmologists to improve or correct vision in patients with cataracts, refractive conditions, and glaucoma.

Cataract Surgery. Our main products are foldable silicone and Collamer® intraocular lenses (IOLs) used after minimally invasive small incision cataract extraction. Over the years, we have expanded our range of products for use in cataract surgery to include:

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

toric silicone IOLs to treat astigmatic abnormalities,

STAARVISC(TM)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, which is used to remove a cataract patient s cloudy lens and has low energy and high vacuum characteristics, and

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

Currently, the majority of our revenues are generated from these products.

Refractive Surgery. In the area of refractive surgery, we have used our biocompatible Collamer material to develop and manufacture the Visian ICL (ICL) and a toric version, the Visian TICL (TICL), to 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 errors. Our goal is to establish the ICL and TICL as widely accepted choices for refractive surgery, making the products significant revenue generators for us over the next four to five years.

The ICL and TICL have not yet been approved for use in the United States. If approved, we believe that the ICL will have a significant market as an alternative to LASIK and other available refractive surgical procedures and could replace cataract surgery products as STAAR s largest source of revenue. The ICL is approved for use in the European Union and in Korea and Canada. The TICL is approved for use in the European Union.

Glaucoma Surgery. 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.

Within each of these segments, 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 allow us to compete more effectively.

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.

The Offering

The selling stockholders listed in the section of this prospectus entitled Selling Stockholders may offer and sell up to 4,100,000 shares of our common stock.

Under this prospectus, the selling stockholders may sell their shares of common stock in the open market at prevailing market prices or in private transactions at negotiated prices. They 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 stockholders 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 entitled Plan of Distribution.

We will not receive any proceeds from the potential sale of the 4,100,000 shares offered by the selling stockholders.

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 three fiscal years and have an accumulated deficit of $60.5 million as of December 31, 2004. There can be no assurance that we will report net income in any future period.

We have only limited working capital.

Our current sources of working capital are sufficient to satisfy our anticipated working capital requirements for fiscal 2005. However, the issues resulting from the FDA Warning Letter of December 22, 2003 and the 483 Observations raise uncertainties about the sufficiency of our working capital for future years and we may have to consider alternative sources of funding. There can be 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 December 31, 2004, we have outstanding balances on the credit facility of a European subsidiary of approximately $3.0 million, based on exchange rates on that date. If our losses continue, we risk defaulting on the terms of our credit facility, particularly as it relates to the maintenance of minimum levels of equity and the payment

of intercompany receivables.

We have only limited access to financing.

Because of our history of losses, there is substantial doubt about our ability to obtain adequate financing on satisfactory terms or at all. Any such financing may involve substantial dilution to existing shareholders.

We have received 483 Inspectional Observations and Warning Letters from the FDA, which until resolved to the satisfaction of the FDA will continue to delay approval of the ICL and could limit our existing business in the United States.

On December 29, 2003 and April 26, 2004, we received Warning Letters issued by the FDA. A copy of the first Warning Letter is attached as Exhibit 99.1 to our Current Report on Form 8-K filed with the Securities and Exchange Commission on January 9, 2004, and a copy of the second Warning Letter is attached as Exhibit 99.1 to our Current Report on Form 8-K filed with the Securities and Exchange Commission on May 6, 2004.

On September 23, 2004, the FDA completed a re-audit of our Monrovia, California manufacturing facility. At the conclusion of the audit, the FDA issued a form FDA 483 Inspectional Observations described more fully in our Current Report on Form 8-K filed with the Securities and Exchange Commission on September 29, 2004.

The Warning Letters and 483 Observations have adversely affected our reputation in the ophthalmic industry and our product sales. Until the FDA is satisfied with our response, it is unlikely to grant us approval to market the ICL and the TICL in the United States and may place restrictions on our domestic lines of business.

Our success depends on the ICL, which has not been approved for use in the United States.

We have devoted significant resources and management attention to the development and introduction of our ICL and TICL. Management believes that the future success of STAAR depends on the approval of the ICL for sale in the United States by the FDA. The ICL is already approved for use in the European Union and Canada and in parts of Asia. The TICL is approved for use in the European Union. In October 2003, the FDA Ophthalmic Devices Panel recommended that the FDA approve, with conditions, specified uses of the ICL. The FDA has not yet acted on this recommendation, and it could decide to reject the Ophthalmic Devices Panel recommendations. Until the FDA is satisfied with our response to its Warning Letter dated December 22, 2003 and its 483 Observations issued on September 23, 2004, it is unlikely to grant us approval to market the ICL and the TICL in the United States. If the FDA does not grant approval of the ICL, or significantly delays its approval, whether because of the issues contained in the Warning Letter, the 483 Observations or otherwise, our prospects for success will be severely diminished.

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

Even if it is approved by the FDA for sale in the United States, the ICL will not reach its full sales potential unless we successfully plan and execute its launch and marketing in the United States. This will present 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. We do not have significant resources 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.

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 is one of our largest sources of revenue. 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 our 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 a new biocompatible lens material, Collamer, to our line of IOLs. We have also introduced new IOL designs, such as the Toric IOL, and have continued to improve and refine the silicone IOL. Sales of these new products, however, have only partially offset declining sales of our silicone IOLs.

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 certain 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 will rely on them, in part, to help introduce the ICL if it is approved. 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. 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. In 2005, we recalled one lot of phaco tubing, manufactured by a third party, due to incorrect labeling. 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 in the past been, and continue to be, subject to product liability claims. As part of our risk management policy, we have obtained third-party product liability insurance coverage. Product liability claims against us may exceed the coverage limits of our insurance policies or cause us to record a self-insured loss. A product liability claim in excess of applicable insurance could have a material adverse effect on our business, financial conditions 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 one of 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 more than 45 countries. Revenues from international operations make up a significant portion of our total revenue. For the year ended December 31, 2004 revenues from international operations were 58%

of total revenues. 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 revenues 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 revenues. 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 revenue.

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 revenue and profitability, or harm our customer relations by delaying product deliveries.

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, local and foreign 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.

Beginning on or about September 1, 2004, multiple class action lawsuits were filed in the United States District Courts for the Central District of California and the District of New Mexico against the Company and its Chief

Executive Officer on behalf of all persons who acquired the Company s securities during various periods between April 3, 2003 and September 28, 2004. The New Mexico action was voluntarily dismissed on January 28, 2005. On December 15, 2004, the Court ordered consolidation of the complaints that had been filed in the United States District Court for the Central District of California and directed that the plaintiffs file a consolidated complaint as soon as practicable. The plaintiffs filed a consolidated amended complaint on April 15, 2005. The amended complaint generally alleges that the defendants 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 intraocular lenses and implantable lenses, and failing to make timely disclosure of significant problems with the lenses, as well as the existence of serious injuries and/or malfunctions attributable to the lenses, thereby artificially inflating the price of our Common Stock. The plaintiffs generally seek to recover compensatory damages, including interest. While we intend to vigorously defend the consolidated lawsuits, and will be filing a motion to dismiss the amended complaint, the lawsuit will require significant attention of management and could result in substantial costs and harm our reputation.

We are currently 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 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 STAAR.

We have granted to the Canon Staar joint venture, a perpetual exclusive license to make and sell products containing our technology in Japan, and to make products containing our technology in China and to sell such products in Japan and China. In addition, we have granted Canon Staar a perpetual non-exclusive license to sell products containing our technology in the rest of the world, subject to the approval of the Board of Directors of the joint venture.

Upon the occurrence of certain events, including the merger, sale of substantially all of the assets or change in the management of any party to the Canon Staar joint venture, the other joint venture partner may have the right to acquire the first party s interest in the joint venture at book value, without terminating the licenses held by the joint venture.

The joint venture agreement, license agreement and a settlement agreement relating to Canon Staar have been filed or incorporated by reference to our Annual Report on Form 10-K for the fiscal year ended December 31, 2004.

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 revenue 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 12.1% of our revenue on research and development (including regulatory and quality assurance expenses) for the year ended December 31, 2004, and we expect to spend between 10-11% of our revenue on an annual basis in the future. 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. 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 or Medicaid. 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 policies 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 revenues. Moreover, our products may not be covered in the future by third-party payors, which would also reduce our revenues.

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 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. Such inspection may result in the FDA ordering changes in our business practices, which changes could be costly and have a material adverse effect on our business and results of operations. In particular, we received Warning Letters from the FDA on December 29, 2003 and April 26, 2004, and FDA 483 Inspectional Observations on September 23, 2004, requiring us to take corrective action as discussed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2004.

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 revenue; to 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 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. We also have a Stockholders Rights Plan, which could discourage a third party from making an offer to acquire us. 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:

only one of the three classes of directors is elected each year;

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 discourage others from making tender offers for our Common Stock or prevent changes in our management.

Future sales of our Common Stock could reduce our stock price.

Our Board of Directors could issue 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 $2.88 to $7.87 per share, during the twelve months ended May 19, 2005. 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 regulatory status, 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

We will not receive any proceeds from the sale of up to 4,100,000 shares of our common stock being offered by the selling stockholders.

SELLING STOCKHOLDERS

The following table shows the names of the selling stockholders, and lists the number of shares of our common stock registered for sale by each of them under this prospectus. It also shows the total number of shares of common stock owned by them before and after the offering, and the percentage of our total outstanding shares represented by these amounts. The table assumes that each selling stockholder will sell all of the common stock being offered by this prospectus for their account. However, the selling stockholders have no obligation to sell any of their shares, so we cannot determine the exact number of shares they actually will sell. None of the selling stockholders has had a material relationship with us within the past three years other than as a result of the selling stockholder s ownership of our securities.

President Street Fund, L.P., ProMed Management, Inc. and SF Capital Partners Ltd. are affiliates of registered broker-dealers. We have been informed by each of these selling security holders that they acquired the securities offered by this prospectus for their own account or the accounts of their affiliates in the ordinary course of their business, and that, at the time they acquired the securities, they had no agreement or understanding, direct or indirect, with any person to distribute the securities.

The table is based on information provided by the selling stockholders, and does not necessarily indicate beneficial ownership for any other purpose. The number of shares of common stock beneficially owned by the selling stockholders is determined in accordance with the rules of the SEC. The term selling stockholders includes the stockholders listed below and their transferees, assignees, pledgees, donees or other successors. The percent of beneficial ownership for each selling stockholder is based on 24,790,638 shares of common stock outstanding as of May 12, 2005.

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 Outstandindg Shares of Common Stock Beneficially Owned After the Offering (2)
Broadwood Partners, L.P. (3)	1,473,830	6.0%	246,000	1,227,830	5.0%
Special Situations Fund III, L.P. (4)	1,061,096	4.3% (5)	755,000	306,096	1.2%
SF Capital Partners Ltd. (6)	700,000	2.8%	650,000	50,000	*
ProMed Offshore Fund II, Ltd. (7)	592,838	2.4% (8)	211,368	381,470	1.5%
Andover Capital Partners, L.P. (9)	516,979	2.1%	148,800	368,179	1.5%
Lubomir Skrobak	493,210	2.0%	80,000	413,210	1.7%
Special Situations Private Equity Fund, L.P. (4)	407,027	1.6% (5)	289,000	118,027	*
Andesite Management, L.P. (10)	374,900	1.5%	115,000	259,900	1.1%
The Conus Fund, L.P. (11)	356,730	1.4% (12)	92,300	264,430	1.1%
Andover Capital Offshore Partners, Ltd. (9)	304,821	1.2%	91,200	213,621	*
Special Situations Cayman Fund, L.P. (4)	301,100	1.2% (5)	215,000	86,100	*
Seamark Fund, L.P. (13)	235,000	*	100,000	135,000	*
Ivy MA Holdings 3, LLC (14)	198,982	* (15)	160,420	38,562	*
Symmetry Capital Qualified Partners L.P. (14)	180,118	* (15)	180,118	----	*
Craig Drill Capital, L.P. (16)	160,000	*	160,000	----	----
Ursus Capital, L.P. (17)	159,800	*	81,000	78,800	*
ProMed Partners, L.P. (7)	152,558	* (8)	62,493	90,065	*

		Percent of			Percent of
The Conus Fund (QP) L.P. (11)	133,427	* (12)	50,000	83,427	*
Cameron QTIP Trust (18)	105,000	*	20,000	85,000	*
Paul Rogan	87,100	*	15,000	72,100	*
President Street Fund, L.P. (19)	80,000	*	50,000	30,000	*
The Conus Fund Offshore Ltd. (20)	78,100	* (12)	29,400	48,700	*
East Hudson Inc. (BVI) (20)	75,100	* (12)	28,300	46,800	*
Symmetry Capital Offshore Fund Ltd. (14)	70,536	* (14)	68,947	1,589	*
Ursus Offshore Ltd. (17)	62,700	*	29,000	33,700	*
Cameron Survivors Trust (18)	55,000	*	10,000	45,000	*
Alpha US Sub Fund V, LLC (14)	53,127	* (15)	43,668	9,459	*
Chad Dunn	51,000	*	15,000	36,000	*
Willis and Daphne Stephens	46,000	*	10,000	36,000	*
ProMed Partners II, L.P. (7)	39,315	* (8)	16,055	23,260	*
SLST Co. Corp (21)	37,575	*	20,000	17,575	*
Symmetry Capital Partners L.P. (14)	28,958	* (15)	28,411	547	*
ProMed Offshore Fund, Ltd. (7)	24,614	* (8)	10,084	14,530	*
Symmetry Parallax Partners L.P. (14)	19,379	* (15)	18,436	943	*

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* 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 that a person has the right to acquire within 60 days of the date of this prospectus 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 each selling stockholder under this 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 this prospectus.

(3) Broadwood Capital, Inc. is the general partner of Broadwood Partners, L.P. As the president of Broadwood Capital, Inc., Neal C. Bradsher exercises voting and dispositive power over the shares held of record by Broadwood Partners, L.P. Mr. Bradsher also beneficially owns 25,900 shares over which he exercises sole voting and dispositive power.

(4) MGP Advisors Limited ("MGP") is the general partner of Special Situations Fund III, L.P. AWM Investment Company, Inc. ("AWM") is the general partner of MGP and the general partner of and investment adviser to Special Situations Cayman Fund, L.P. MG Advisers, LLC ("MG") is the general partner of and investment adviser to Special Situations Private Equity Fund, L.P. As the principal owners of MGP, AWM, and MG, Austin W. Marxe and David M. Greenhouse exercise voting and dispositive power over the shares held of record by Special Situations Cayman Fund, L.P., Special Situations Fund III, L.P., and Special Situations Private Equity Fund, L.P.

(5) The 1,769,223 total shares over which the persons described in footnote (4) exercise voting and dispositive power comprise approximately 7.1% of the outstanding shares of STAAR Surgical Company.

(6) Michael A. Roth and Brian J. Stark possess voting and dispositive power over all of the shares owned by SF Capital Partners Ltd. SF Capital Partners Ltd. is affiliated with the registered broker dealers Reliant Trading and Shepherd Trading Limited.

(7) The management of these funds is directed by ProMed Management, Inc. through the two investment managers, David Musket and Barry Kurokawa. Mr. Musket is a principal of Musket Research Associates, a registered broker dealer, and Mr. Kurokawa is a registered representative of Musket Research Associates.

(8) The 809,325 total shares over which Mr. Musket and Mr. Kurokawa exercise voting and dispositive power comprise approximately 3.3% of the outstanding shares of STAAR Surgical Company.

(9) David Glancy as managing director of Andover Capital Partners, L.P. and president of Andover Capital Offshore Partners, Ltd., exercises voting and dispositive power over the shares held of record by Andover Capital Partners, L.P. and Andover Capital Offshore Partners, Ltd.

(10) Includes 70,873 shares held before this offering and 47,058 shares held after this offering by Andesite Life Sciences I, L.P., 51,263 shares held before this offering and 34,018 shares held after this offering by Andesite Life Sciences II, L.P., and 252,764 shares held before this offering and 178,824 shares held after this offering by Andesite Life Sciences Ltd. The management of these funds is directed by Andesite Management, L.P. As managing member of Andesite Management, L.P., Hamilton Mehlman exercises sole voting and investment power over the shares.

(11) Conus Capital LLC is the general partner of The Conus Fund, L.P. and The Conus Fund (QP) L.P. As managing member of Conus Capital LLC, Andrew Zacks exercises voting and dispositive power over the shares held of record by The Conus Fund, L.P. and The Conus Fund (QP) L.P.

(12) The 643,357 total shares over which Andrew Zacks, as managing director of Conus Partners, Inc. and as managing member of Conus Capital LLC exercises voting and dispositive power comprise approximately 2.6% of the outstanding shares of STAAR Surgical Company.

(13) Seamark Capital, L.P., is the general partner of Seamark Fund, L.P. As the managing partner of Seamark Fund, L.P., John D. Fraser exercises voting and dispositive power of the shares held of record by Seamark Fund, L.P.

(14) The management of these funds is directed by Symmetry Capital Management, LLC. As portfolio manager of Symmetry Capital Management, LLC, Kellie Seringer exercises voting and dispositive power over the shares held of record by Alpha US Sub Fund V, LLC, Ivy MA Holdings 3, LLC, Symmetry Capital Offshore Fund Ltd., Symmetry Capital Partners L.P., Symmetry Capital Qualified Partners, L.P. and Symmetry Parallax Partners L.P.

(15) The 551,100 total shares over which Kellie Seringer, as portfolio manager of Symmetry Capital Management, LLC exercises voting and dispositive power comprise approximately 2.6% of the outstanding shares of STAAR Surgical Company.

(16) Craig Drill Capital, LLC is the general partner of Craig Drill Capital, L.P. As the manager of Craig Drill Capital, LLC, Craig A. Drill exercises voting and dispositive power over the shares held of record by Craig Drill Capital, L.P.

(17) Evan Sturza, as the managing director of Ursus Capital L.P. and president of Ursus Offshore Ltd., exercises voting power and dispositive power over the shares held of record by Ursus Capital L.P. and Ursus Offshore Ltd.

(18) Ralph Cameron, as the trustee of the Cameron QTIP Trust and the Cameron Survivors Trust, exercises voting and dispositive power over the shares held of record by Cameron QTIP Trust and Cameron Survivors Trust.

(19) Francis A. Mlynarczyk, Jr. is the general partner of President Street Fund, L.P., and exercises voting and dispositive power over the shares held of record by President Street Fund, L.P. In addition, Mr. Mlynarczyk, and his wife, Rebecca K. Mlynarczyk, beneficially own a total of 7,500 shares over which they jointly exercise voting and dispositive power. Mr. Mlynarczyk is the chief operating officer of Brimberg & Co., L.P., a registered broker dealer.

(20) Conus Partners, Inc. is the investment manager of East Hudson, Inc. (BVI) and The Conus Fund Offshore Ltd. As managing director of Conus Partners, Inc., Andrew Zacks exercises voting and dispositive power over the shares held of record by East Hudson Inc. (BVI) and The Conus Fund Offshore Ltd.

(21) Steven The, as the president of SLST Co. Corp, exercises voting and dispositive power over the shares held of record by SLST Co. Corp.

PLAN OF DISTRIBUTION

The selling stockholders and their successors, including their transferees, pledgees or donees, may sell the shares covered by this prospectus from time to time for their own accounts. They will act independently of us in making decisions regarding the timing, manner and size of each sale. They may sell their shares on the Nasdaq National Market or other exchanges, in the over-the-counter market or in privately negotiated transactions. They may sell their shares directly or through underwriters, broker-dealers or agents, who may receive compensation in the form of discounts, concessions, or commissions from the selling stockholders 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 their 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 this
ordinary brokerage transactions and transactions in which the broker solicits purchasers, which may include long or short sales made after the effectiveness of the registration statement of which this 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 this 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 this prospectus.

The selling stockholders 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 stockholders.

The selling stockholders also may sell shares short and redeliver the shares to close out these short positions. The selling stockholders 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 this prospectus (which may be amended or supplemented to reflect the transaction). The selling stockholders also may

loan or pledge the shares to a broker-dealer or another financial institution. If a 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 this 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 stockholders. 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 stockholders 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 purchased by them may be deemed to be underwriting discounts or commissions under the Securities Act.

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

We have agreed to maintain the effectiveness of the registration statement of which this prospectus is a part until the earliest to occur of the following:

April 6, 2007;

the date on which all of the selling stockholders can sell the shares offered in this prospectus without registration under Rule 144(k); or

the date on which all of shares offered have been sold by the selling stockholders.

We may suspend the selling stockholders rights to resell shares under this prospectus for limited periods if required to do so by regulatory action or because material information or events affecting us are not adequately disclosed in the then available prospectus.

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 specified legal and accounting fees. The selling stockholders 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 any selling stockholder. We have also agreed to indemnify the selling stockholders against liabilities, including certain liabilities under the Securities Act.

The selling stockholders 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 stockholders may be deemed to be underwriters within the meaning of Section 2(11) of the Securities Act, the selling stockholders 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 stockholders, 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 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 stockholders 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 stockholders.

We will make copies of this prospectus available to the selling stockholders and have informed the selling stockholders 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.

LEGAL MATTERS

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

EXPERTS

The financial statements and schedules incorporated by reference in this 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 this prospectus. This prospectus does 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 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 on payment of the fees prescribed by the SEC.

We will furnish without charge to each person to whom a copy of this prospectus is delivered, on written or oral request, a copy of the information that has been incorporated by reference into this prospectus (except exhibits, unless they are specifically incorporated by reference into this 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.

INFORMATION INCORPORATED BY REFERENCE

The Securities and Exchange Commission, or SEC, allows us to incorporate by reference in this 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 this 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 31, 2004, as amended on April 21, 2005 and May 10, 2005;

our Quarterly Report on Form 10-Q for the period ended April 1, 2005;

our Current Reports on Form 8-K filed with the SEC on January 21, 2005, April 5, 2005, April 13, 2005 and May 4, 2005;

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; and

The description of our Stockholders Rights Plan contained in Amendment No. 1 to our registration statement on Form 8-A/A filed with the SEC on April 18, 2003, including Amendment No. 1 to our Stockholders Rights Plan contained in Exhibit 4.7 to our Quarterly Report on Form 10-K for our quarter ended April 4, 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.