

STAAR SURGICAL COMPANY

Form 424B3

July 02, 2004

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This filing is made pursuant to Rule 424(b)(3) under the Securities Act of 1933 in connection with Registration No. 333-116901

PROSPECTUS

STAAR Surgical Company

2,000,000 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 2,000,000 shares being offered by the selling stockholders.

Our common stock trades on the Nasdaq National Market under the symbol STAA. On June 30, 2004, the closing sales price for our common stock on the Nasdaq National Market was \$7.80 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 July 1, 2004.

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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 and STAAR refer to STAAR Surgical 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 the 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.

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PROSPECTUS SUMMARY

STAAR Surgical Company

STAAR is a provider of products for eye care professionals operating in three sectors of the ophthalmic products industry: cataract surgery, refractive surgery and glaucoma surgery. Our overall mission is to develop, manufacture and market innovative, high margin visual implants that improve a patient's quality of vision.

Cataract Surgery. Initially, our main product was a foldable, implantable silicone lens for use after small incision cataract extraction. The production and sale of intraocular lenses, or IOLs, remains our core business. Since that time we have expanded our range of IOLs and other products used in cataract surgery to also include the following:

Silicone Toric IOLs, used in cataract surgery to treat astigmatic vision abnormalities;

Collamer® IOLs, made of a proprietary collagen-based material, which are used in cataract surgery to treat spherical vision abnormalities;

STAARVISC II, a viscoelastic material;

the SonicWAVE Phacoemulsification System, which is used to remove a cataract patient's diseased lens and has unique low energy and high vacuum characteristics; and

Cruise Control, a disposable filter used during phacoemulsification.

These give us a rounded portfolio of products to meet the needs of the cataract surgeon. Currently, these products generate the majority of our revenues.

Refractive Surgery. In the area of refractive surgery, we have used our uniquely biocompatible Collamer material to develop and manufacture the VISIAN ICL or ICL®, and the VISIAN TICL or 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.

The ICL has not yet been approved for use in the United States. On October 3, 2003, the Ophthalmic Devices Panel of the Center for Devices and Radiological Health of the United States Food and Drug Administration, or FDA, recommended that, with specified conditions, the FDA approve the ICL for use in correcting myopia in the range of -3 to -15 diopters and reducing myopia in the range of -15 to -20 diopters. If approved, STAAR believes that the ICL will have a significant market as an alternative to LASIK and other available refractive surgical procedures and will likely replace cataract surgery products as STAAR's largest source of revenue.

We received Warning Letters issued by the FDA, dated December 22, 2003 and April 23, 2004, which outlined deficiencies related to our manufacturing and quality assurance systems

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that were identified during inspection audits of our Monrovia, California facility. We are aggressively pursuing corrective actions to remedy the issues, which are not directly related to the ICL. However, until the FDA is satisfied with our response, it will not grant approval to market the ICL in the United States and we may face FDA restrictions on our established domestic lines of business. See Risk Factors.

The ICL is approved for use in the countries comprising the European Union and in Korea and Canada. The TICL is in clinical trials in the United States, and is approved for use in the countries comprising the European Union.

Glaucoma Surgery. STAAR has developed the AquaFlow Collagen Glaucoma Drainage Device, also referred to as the AquaFlow 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 sectors, 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 2,000,000 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 2,000,000 shares offered by the selling stockholders.

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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.

We have reported losses in each of the last three fiscal years and have an accumulated deficit of \$50.4 million as of April 2, 2004. If losses from operations continue, they could adversely affect the market price for our Common Stock and our ability to obtain new financing.

We have received Warning Letters from the FDA, which will delay approval of the ICL and could limit our existing business in the United States.

We have received Warning Letters issued by the FDA, dated December 22, 2003 and April 23, 2004. While we are acting to correct the deficiencies identified in the Warning Letters, until the FDA is satisfied with our response, we will not be granted approval to market the ICL in the United States and we may face FDA restrictions on our established domestic lines of business. We cannot provide assurance that the FDA's review of our practices and procedures will not result in additional Warning Letters or other regulatory action. Even if the FDA approves our corrective measures, the publication of the Warning Letters or similar actions in the future could harm our reputation and reduce sales.

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. Our management believes that the future success of STAAR depends on the approval of the ICL by the FDA and a successful launch of the ICL in North America. The ICL is already approved for use in the countries comprising the European Union and Canada and in parts of Asia. The TICL is approved for use in the countries comprising the European Union. On October 3, 2003 the FDA Advisory Committee 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 or modify the Advisory Committee's recommendations. Until the FDA is satisfied with our response to its Warning Letters, we will not be granted approval to market the ICL in the United States. If the FDA does not grant

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approval of the ICL, or significantly delays its approval, whether because of the issues contained in the Warning Letters or otherwise, our prospects for success will be severely diminished.

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

Even if it is approved by the FDA, 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 unlimited 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 remains our largest source 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 STAAR 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 have limited access to credit and have been in default of the terms of our loan agreements.

As of April 2, 2004, we failed to comply with a covenant under our principal foreign loan agreement, which prohibits the repayment of loans made by STAAR to its Swiss subsidiary without the prior consent of the lender. Accordingly, we had to obtain a waiver from our lender. As of April 2, 2004, we have outstanding balances on the loans of our European subsidiaries of approximately \$3.0 million, based on exchange rates on that date. In the near term, we believe that sufficient cash to fund operations and current growth plans will be provided by cash generated from operations and the proceeds of our June 10, 2004 private placement, in which we raised proceeds, net of placement agent fees, of approximately \$11,750,000 by selling 2,000,000 shares of our common stock. However, it is likely that we will also need access to credit to finance operations and fund future growth. Because of our history of losses we may not be able secure adequate financing for these purposes on terms that are favorable to us or on any terms.

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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 will rely on them, in part, to help introduce the ICL if it is approved. However, in an effort to balance the risks associated with a purely independent sales force, we have introduced direct application specialists to assist in proctoring and surgeon training to ensure physician compliance and enhance patient outcomes with our high technology products. If the introduction of direct application specialists is not successful, or 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. Recalls significantly impacted our revenue in 2001 when, in separate instances, we voluntarily recalled our three-piece Collamer lens and some of our silicone lenses, and as a result wrote down approximately \$3.4 million in inventory in that year. In January 2004, we voluntarily recalled selected lots of IOL cartridges. In February 2004, in an action the FDA considers a recall but where there is 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. 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 compete with much larger companies.

Our competitors, including Alcon, Inc., Advanced Medical Optics, Inc. (AMO), Bausch & Lomb, Inc., and Pfizer, Inc. 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

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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 facility in Monrovia, California or our facility in Nidau, 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.

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 new Aquaflow Device.

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

We spent 10.1% of our revenue on research and development during the year ended January 2, 2004, and we expect to spend comparable amounts annually 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

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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 profits. 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 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.

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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. These inspections 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 dated December 22, 2003 and April 23, 2004, requiring us to take corrective action.

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.

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

Our products are sold in more than 35 countries. Revenues from international operations make up a significant portion of our total revenue. For the quarter ended April 2, 2004, revenues from international operations were 59% of total revenues. The results of operations and the financial position of some 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

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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 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 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.

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

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application. Patents covering our products will expire from this year through the next 20 years. When a patent expires, 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.

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 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.

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.

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

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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 call a special meeting of stockholders; and

stockholders must give advance notice to nominate directors.

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

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

Future sales of our common stock may depress our stock price.

The market price of our common stock could be subject to downward price pressure as a result of sales of our recent private placement of 2,000,000 shares of common stock, which have been registered for resale, or the perception that these sales could occur. In addition, the perception that we might conduct similar private placements followed by public offering of the privately placed shares could make it more difficult for us to raise funds through future offerings of common stock. As of June 30, 2004, there were 20,493,522 shares of our common stock outstanding, with another 2,657,646 shares of common stock issuable on exercise of options granted under our stock option plans or under agreements with our senior officers. Some of the stock underlying these options has been registered for resale with the SEC.

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

Our stock price has fluctuated widely, ranging from \$6.25 to \$15.44 within the past year, as of June 30, 2004. 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

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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 2,000,000 shares of our common stock being offered by the selling stockholders.

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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 the stockholder's 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.

Fortis Investment Management USA, Inc., 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 accounts 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 20,493,522 shares of common stock outstanding as of June 30, 2004.

| 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) |
|---|--|---|---|---|--|
| Andesite Management, L.P.(3) | 58,866 | * | 50,000 | 8,866 | * |
| Colonial Fund, LLC(4) | 150,000 | * | 150,000 | 0 | |
| Domain Public Equity Partners, L.P.(5) | 100,000 | * | 100,000 | 0 | |
| Fortis Investment Management USA, Inc.(6) | 580,100 | 2.8% | 125,000 | 455,100 | 2.2% |
| Heartland Group, Inc.(7) | 1,100,000 | 5.4% | 300,000 | 800,000 | 3.9% |
| ProMed Management, Inc.(8) | 112,700 | * | 100,000 | 12,700 | * |
| Sagitta Asset Management Ltd.(9) | 50,000 | * | 50,000 | 0 | |
| SF Capital Partners Ltd.(10) | 50,000 | * | 50,000 | 0 | |

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| | | | | |
|--|---------|----------|---------|---|
| Special Situations Cayman Fund L.P. (11) | 144,000 | *(12) | 144,000 | 0 |
| Special Situations Fund III, L.P. (11) | 480,000 | 2.3%(12) | 480,000 | 0 |
| Special Situations Private Equity Fund, L.P. (11) | 176,000 | *(12) | 176,000 | 0 |

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| 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 Outstanding Shares of Common Stock Beneficially Owned After the Offering (2) | Percent of Outstanding Shares of Common Stock Beneficially Owned After the Offering (2) |
|------------------------------------|--|---|---|---|--|
| Ursus Capital, L.P. (13) | 74,000 | * | 30,200 | 43,800 | * |
| Ursus Offshore, Ltd. (13) | 53,500 | * | 19,800 | 33,700 | * |
| Zeke, L.P. (14) | 225,000 | 1.1% | 225,000 | 0 | |

* 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) Includes 14,750 shares held by Andesite Life Sciences I, L.P., 8,650 shares held by Andesite Life Sciences II, L.P., and 26,600 shares held 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.
- (4) As President of Colonial Fund LLC, Cary G. Brody exercises voting and investment power over the shares.
- (5) Domain Public Equity Associates, LLC is the General Partner of Domain Public Equity Partners L.P. The Managing Members of Domain Public Equity Associates, LLC, Nicole Vitullo and Domain Associates, LLC, share voting and investment power over the shares.
- (6) Includes 428,850 shares held before this offering and 335,100 shares held after this offering by Fortis L Fund Equity Pharma World and 151,250 shares held before this offering and 120,000 shares held after this offering

by Fortis L Opportunity World. The management of these funds is directed by Fortis Investment Management USA, Inc., which is a registered investment advisor under the Investment Advisors Act of 1940, IARD/CRD No. 105085.

- (7) The 300,000 shares beneficially owned by Heartland Group, Inc. are held of record by Heartland Value Fund. Heartland Value Fund is a registered investment company under the Investment Company Act of 1940.
- (8) Includes 12,935 shares held before this offering and 1,445 shares held after this offering by ProMed Offshore Fund, Ltd., 80,315 shares held before this offering and 9,055 shares held after this offering by ProMed Partners, L.P. and 19,450 shares held before this offering and 2,200 shares held after this offering by ProMed Partners II, L.P. 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.
- (9) Includes 40,000 shares held by The Sagitta Americas Mid Cap Growth Fund, 8,000 shares held by The Mariner Fund Limited, and 2,000 shares held by The Salix Healthcare Fund Limited. The management of these funds is directed by Sagitta Asset Management Limited, which is a registered investment advisor under the Investment Advisors Act of 1940, IARD/CRD No. 113639.

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- (10) Michael A. Roth and Brian J. Stark are the founding members and direct the management of Staro Asset Management, LLC, a Wisconsin limited liability company (Staro), which acts as investment manager and has sole power to direct the management of SF Capital Partners Ltd. Through Staro, Messrs. Roth and Stark possess sole 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.
- (11) MGP Advisors Limited (MPG) 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.
- (12) The 800,000 total shares over which the persons described in footnote (11) exercise voting and dispositive power comprise approximately 3.9% of the outstanding shares of STAAR Surgical Company.
- (13) Evan Sturza, as the Managing Director of Ursus Capital L.P. and President of Ursus Offshore Ltd., exercises voting and dispositive power over the shares held of record by Ursus Capital L.P. and Ursus Offshore Ltd.
- (14) Edward N. Antoin, as General Partner of Zeke, L.P., exercises voting and dispositive power over the shares held of record by Zeke, L.P.

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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 stockholders 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 prospectus;

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.

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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:

June 10, 2006;

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.

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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 of which this prospectus is a part 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 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 consolidated financial statements and the related consolidated financial statement schedule incorporated in this prospectus by reference from our Annual Report on Form 10-K for the fiscal year ended January 2, 2004, as amended, have been audited by BDO Seidman, LLP, STAAR's independent registered public accounting firm, as stated in their report dated March 3, 2004, which is incorporated herein by reference, and have been so incorporated in reliance on the report of that firm given on their authority as experts in accounting and auditing.

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

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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 January 2, 2004;

our Quarterly Report on Form 10-Q for the fiscal quarter ended April 2, 2004;

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our Current Report on Form 8-K filed with the SEC on January 9, 2004; our Current Report on Form 8-K filed with the SEC on May 6, 2004; our Current Report on Form 8-K filed with the SEC on June 9, 2004; and our Current Report on Form 8-K filed with the SEC on June 18, 2004;

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, 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.