STAAR SURGICAL COMPANY
Form S-3/A
January 14, 2004

As filed with the Securities and Exchange Commission on January 14, 2004.

Registration No. 333-111140

UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

AMENDMENT NO. 1
TO
FORM S-3

REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933
STAAR SURGICAL COMPANY
(Exact name of registrant as specified in its charter)

Delaware	95-3797439
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

1911 Walker Avenue
Monrovia, California 91016
(626) 303-7902

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

John Bily
Chief Financial Officer
STAAR Surgical Company
1911 Walker Avenue
Monrovia, California 91016
(626) 303-7902
(Name, address, including zip code, and telephone number, including area code, of Agent for Service)

Copies to:
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Approximate date of commencement of proposed sale to the public: From time to time after the effective date of this Registration Statement.

If the only securities being registered on this form are being offered pursuant to dividend or interest reinvestment plans, please check the following box. |_|

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, other than securities offered only in connection with dividend or interest reinvestment plans, check the following box. |X|

If this form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. |_| _____

If this form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.|_|_____

If delivery of the prospectus is expected to be made pursuant to Rule 434, please check the following box. |_|_____

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended (the "Securities Act"), or until this Registration Statement shall become effective on such date as the Securities and Exchange Commission (the "SEC"), acting pursuant to said Section 8(a), may determine.

PROSPECTUS

[STAAR LOGO]
STAAR Surgical Company

120,000 Shares

Common Stock

($0.01 Par Value)

This is an offering of common stock of STAAR Surgical Company, or STAAR. All of the shares are being offered by the selling stockholder listed in the section of this prospectus entitled "Selling Stockholder." We will not receive any of the proceeds from the sale of the 120,000 shares being offered by the selling stockholder.

Our common stock trades on the Nasdaq National Market under the symbol "STAA." On January 12, 2004, the closing sales price for our common stock on the Nasdaq National Market was $9.00 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 January 14, 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 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 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(R) IOLs, made of a proprietary collagen-based material, which are used in cataract surgery to treat spherical vision abnormalities;
- STAARVISC(TM)II, a viscoelastic material;
- the SonicWAVE(TM)Phacoemulsification System, which is used to remove a cataract patient's diseased lens and has unique low energy and high vacuum characteristics; and
- UltraVac(TM) V1 tubing for use with certain Venturi-type phacoemulsification machines.

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 Implantable Contact Lens(TM), or ICL(R), and the Toric Implantable Contact Lens, or TICL(R), 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 diseased 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, but in May 2003, STAAR submitted the final module of its Pre-Market Approval Submission for the ICL to the United States Food and Drug Administration (the "FDA"). On October 3, 2003, the FDA Ophthalmic Devices Panel of the Center for Devices and Radiological Health recommended that, with certain 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. On December 29, 2003, we received a Warning Letter issued by the FDA. While we are acting to quickly correct the deficiencies identified in the Warning Letter, 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. 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(TM) Collagen Glaucoma Drainage Device (the "AquaFlow Device") as a surgical treatment for glaucoma surgery. The AquaFlow Device, approved by the FDA in July 2001, is 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 stockholder listed in the section of this prospectus entitled "Selling Stockholder" may offer and sell up to 120,000 shares of our common stock.

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

We will not receive any proceeds from the potential sale of the 120,000 shares offered by the selling stockholder.

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 $45.6 million as of October 3, 2003. If losses from operations continue, they could adversely affect the market price for our common stock and our ability to obtain new financing. In June 2000, we began implementing a restructuring plan aimed at reducing costs and improving operating efficiency. In connection with this plan, we recognized pre-tax charges to earnings of $15.3 million, $7.8 million, and $1.5 million in fiscal 2000, 2001, and 2002. While the restructuring plan has generally improved our profit margins, we cannot be certain that we will succeed in restoring our profitability.

We have been in default of the terms of our domestic loan agreement and have limited access to credit.

We have recently failed to comply with some of the financial covenants of our principal domestic loan agreement, including a failure to maintain minimum levels of tangible net worth in the first fiscal quarter of 2003, a failure to maintain minimum levels of operating income in the second and third fiscal quarters of 2002 and a failure to maintain minimum levels of cash flow in the second fiscal quarter of 2002. Accordingly, we have had to obtain waivers from our lender or modifications of our loan agreement. As of June 19, 2003, we have paid off and eliminated our domestic loan, and have outstanding balances on the loans of our European subsidiaries of approximately $3.3 million, based on exchange rates on October 3, 2003. 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 11, 2003 private placement, in which we raised proceeds, net of placement agent fees, of approximately $9 million by selling 1,000,000 shares of our common stock. However, it is likely that in the future we will 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.

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

On December 29, 2003, we received a Warning Letter issued by the FDA. While we are acting to quickly correct the deficiencies identified in the Warning Letter, 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. Even if the FDA approves our corrective action, the publication of the Warning Letter or similar actions in the future could harm our reputation and reduce sales. A copy of the 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.

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. In May 2003, we submitted the final module of our Pre-Market Approval Submission for the ICL to the FDA, and on October 3, 2003 the FDA Advisory Committee recommended that 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 Advisory Committee's recommendations. Until the FDA is satisfied with our response to the Warning Letter issued by the FDA on December 22, 2003, we will not be granted approval to market the ICL 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 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, pioneered cartridge-injector systems for lens insertion, 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 reduce costs and bring our products to a wider market, we have entered into long-term agreements with several 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, we are also introducing direct application specialists to assist in proctoring and surgeon training to ensure physician compliance and enhance patient outcomes as a means of growing this segment of the market. 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.

Implantable 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 certain 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, although the impact of that recall on the Company's results of operations is not expected to be material. 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 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 Bausch & Lomb, Inc., Advanced Medical Optics, Inc. (AMO), Alcon, Inc., Pfizer, Inc. and the CIBA Vision division of Novartis AG, have much greater financial resources than we do and some of them have large international markets for a full suite of ophthalmic products. Their greater resources for research, development and marketing, and their greater capacity to offer comprehensive products and equipment to providers, make it difficult for us to compete. We have lost significant market share to some of our competitors.

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

We manufacture all of our products either at our 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 10.3% of our revenue on research and development during the first nine months of 2003, 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 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.

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.

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 39 countries. Revenues from international operations make up a significant portion of our total revenue. For the nine months ended October 3, 2003 revenues from international operations were 53%. The results of operations and the financial position 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. In 2003, our most significant currency exposures were 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 had a material adverse effect on our operating margins and profitability in the past, and may have similar effects in the future.

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 have experienced currency fluctuations, inflation and volatile economic conditions, which have affected our profitability in the past in several markets, including Japan, Switzerland, the European Union and Australia, and we may experience such effects in the future.

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 the raw material for the STAARVISC II 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 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.

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

Our manufacturing, research and development practices involve the controlled use of hazardous materials. We are subject to federal, state and

local laws and regulations in the various jurisdictions in which we have operations governing the use, manufacturing, storage, handling and disposal of these materials and certain waste products. Although we believe that our safety and environmental procedures for handling and disposing of these materials comply with legally prescribed standards, we cannot completely eliminate the risk of accidental contamination or injury from these materials. Remedial environmental actions could require us to incur substantial unexpected costs, which would materially and adversely affect our results of operations. If we were involved in a major environmental accident or found to be in substantial non-compliance with applicable environmental laws, we could be held liable for damages or penalized with fines.

We risk losses through litigation.

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 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 1,000,000 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 January 12, 2004, there were 18,407,590 shares of our common stock outstanding, with another 2,536,466 shares of common stock issuable upon exercise of options granted under our stock option plans or under certain 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 $3.05 to $15.44 within the past year, as of January 12, 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 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 120,000 shares of our common stock being offered by the selling stockholder.

SELLING STOCKHOLDER

The following table lists the number of shares of our common stock registered for sale by the selling stockholder under this prospectus. It also shows the total number of shares of common stock owned by him before and after the offering, and the percentage of our total outstanding shares represented by these amounts. The table assumes that the selling stockholder will sell all of the common stock being offered by this prospectus for his account. However, the selling stockholder has no obligation to sell any of his shares, so we cannot determine the exact number of shares he actually will sell.

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

The table is based on information provided by the selling stockholder, and does not necessarily indicate beneficial ownership for any other purpose. The number of shares of common stock beneficially owned by the selling stockholder is determined in accordance with the rules of the SEC. The term "selling stockholder" includes the stockholder listed below and his transferees, assignees, pledgees, donees or other successors. The percent of beneficial ownership for the selling stockholder is based on 18,407,590 shares of common stock outstanding as of January 12, 2004.

	Number of	Percent of Outstanding	Number of	Number of

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

* Represents less than 1% of the outstanding shares.

(1) The number and percentage of shares beneficially owned is determined in accordance with Rule 13d-3 of the Securities Exchange Act of 1934, as amended, and the information is not necessarily indicative of beneficial ownership for any other purpose. Under Rule 13d-3, the number of shares beneficially owned includes any shares as to which a person has sole or shared voting power or investment power. Shares which a person has the right to acquire within 60 days of the date of this prospectus are included in the shares owned by that person and are treated as outstanding for purposes of calculating the ownership percentage of that person, but not for any other person.

(2) Assumes that all shares being offered by the selling stockholder under 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 options to purchase up to 40,000 shares of STAAR Surgical Company common stock.

PLAN OF DISTRIBUTION

The selling stockholder and his successors, including his transferees, pledgees or donees, may sell the shares covered by this prospectus from time to time for his own account. He will act independently of us in making decisions regarding the timing, manner and size of each sale. He may sell his shares on the Nasdaq National Market or other exchanges, in the over-the-counter market or in privately negotiated transactions. He may sell his shares directly or through underwriters, broker-dealers or agents, who may receive compensation in the form of discounts, concessions, or commissions from the selling stockholder or from the purchasers of the shares. The compensation received by a particular underwriter, broker, dealer or agent might exceed customary commissions.

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

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

- purchases by a broker or dealer as a principal and resale by that broker or dealer for its own account under 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 which 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 stockholder may enter into hedging transactions with broker-dealers in connection with distributions of the shares or otherwise. In these transactions, broker-dealers may engage in short sales of common stock in the course of hedging the positions they assume with the selling stockholder.

The selling stockholder also may sell shares short and redeliver the shares to close out such short positions. He may enter into options or other transactions with broker-dealers that require the delivery to the broker-dealer of the shares. The broker-dealer may then resell or otherwise transfer the shares covered by this prospectus (which may be amended or supplemented to reflect the transaction). The selling stockholder also may loan or pledge the shares to a broker-dealer or another financial institution. If the selling stockholder defaults on the loan or the obligation secured by the pledge, the broker-dealer or institution may sell the shares so loaned or pledged under 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 stockholder or his successors. Broker-dealers or agents may also receive compensation from the purchasers for whom they act as agents or to whom they sell as principals, or both. Compensation received by a particular broker-dealer might be in excess of customary commissions and will be in amounts to be negotiated in connection with the sale.

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

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

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

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

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

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

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

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

LEGAL MATTERS

The validity of the issuance of the shares of common stock in this offering will be passed upon 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 3, 2003, as amended, have been audited by BDO Seidman, LLP, independent certified public accountants, as stated in their report dated February 21, 2003 (except for Note

18, as to which the report is dated March 26, 2003, and Notes 6 and 19, as to which the report is dated November 17, 2003), which is incorporated herein by reference, and have been so incorporated in reliance upon the report of such firm given upon 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 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 upon 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, upon 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 3, 2003, as amended;

- our Quarterly Reports on Form 10-Q for our fiscal quarters ended April 4, 2003, as amended, July 4, 2003, as amended and October 3, 2003;

- our Current Reports on Form 8-K filed with the SEC on March 31, 2003, as amended, June 6, 2003, June 13, 2003, August 25, 2003 (as amended on September 4, 2003 and November 7, 2003) and January 9, 2004; and

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

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

PART II
INFORMATION NOT REQUIRED IN PROSPECTUS

Item 14. Other Expenses of Issuance and Distribution.

The following table sets forth the costs and expenses payable by the Registrant in connection with the sale of common stock being registered. All amounts are estimates except the Securities and Exchange Commission registration fee.

Securities and Exchange Commission registration fee.....	$ 105
Nasdaq National Market additional listing fee.....	0
Accounting fees and expenses.....	5,000
Legal fees and expenses.....	5,000
Printing and related fees.....	100
Miscellaneous.....	200
Total.....	$ 10,405

Item 15. Indemnification of Directors and Officers.

Section 145 of the Delaware General Corporation Law provides that a corporation may indemnify directors and officers as well as other employees and individuals against expenses (including attorneys' fees), judgments, fines and amounts paid in settlement in connection with specified actions, suits or proceedings, whether civil, criminal, administrative or investigative (other than an action by or in the right of the corporation or a derivative action), if they acted in good faith and in a manner they reasonably believed to be in or not opposed to the best interests of the corporation and, with respect to any criminal action or proceedings, had no reasonable cause to believe their conduct was unlawful.

A similar standard is applicable in the case of derivative actions, except that indemnification only extends to expenses (including attorneys' fees) actually and reasonably incurred in connection with the defense or settlement of such action, and the statute requires court approval before there can be any indemnification where the person seeking indemnification has been found liable to the corporation. The statute provides that it is not exclusive of other indemnification that may be granted by a corporation's certificate of incorporation, bylaws, disinterested director vote, stockholder vote, agreement or otherwise.

As permitted by Section 145 of the Delaware General Corporation Law, Article VIII of our certificate of incorporation, as amended, provides:

> "The corporation shall to the fullest extent permitted by Section 145 of the Delaware General Corporation Law indemnify all persons whom it may indemnify pursuant thereto."

Our by-laws provide for indemnification of officers and directors to the fullest extent permitted by Delaware law. In addition, the Registrant has, and intends in the future to enter into, agreements to provide indemnification for directors and officers in addition to that provided for in the by-laws.

We maintain an insurance policy pursuant to which our directors and officers are insured, within the limits and subject to the limitations of the policy, against certain expenses in connection with the defense of certain claims, actions, suits or proceedings, and certain liabilities which might be imposed as a result of such claims, actions, suits or proceedings, that may be brought against them by reason of their being or having been directors or officers.

We generally enter into agreements with our executive officers and directors to indemnify them to the fullest extent permitted under the Delaware General Corporation Law.

Item 16. Exhibits.

Exhibit Number	Description of Exhibit
4.1	Form of Certificate for Common Stock, par value $0.01 per share (incorporat Exhibit 4.1 to Amendment No. 1 to the Company's Registration Statement on F with the Commission on April 18, 2003).
5.1	Opinion of Sheppard, Mullin, Richter & Hampton, LLP
23.1	Consent of Sheppard, Mullin, Richter & Hampton, LLP (included in its opinio Exhibit 5.1)
23.2	Consent of BDO Seidman, LLP
24.1*	Power of Attorney (See p. II-4)

* Previously filed.

Item 17. Undertakings.

a. The undersigned registrant hereby undertakes:

1. To file, during any period in which offers or sales are being made, a post-effective amendment to this Registration Statement:

i. To include any prospectus required by Section 10(a)(3) of the Securities Act of 1933, as amended (the "Securities Act");

ii. To reflect in the prospectus any facts or events arising after the effective date of this Registration Statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in this Registration Statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than a 20 percent change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement; and

iii. To include any material information with respect to the plan of distribution not previously disclosed in this Registration Statement or any material change to such information in this Registration Statement;

provided, however, that paragraphs (a)(1)(i) and (a)(1)(ii) do not apply if the registration statement is on Form S-3, Form S-8 or Form F-3, and the information required to be included in a post-effective amendment by those paragraphs is contained in periodic reports filed with or furnished to the Commission by the registrant pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended (the "Exchange Act") that are incorporated by reference in this Registration Statement.

2. That, for the purpose of determining any liability under the Securities Act, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

3. To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

b. The undersigned registrant hereby undertakes that, for purposes of determining any liability under the Securities Act, each filing of the registrant's annual report pursuant to Section 13(a) or 15(d) of the Exchange Act (and, where applicable, each filing of an employee benefit plan's annual report pursuant to Section 15(d) of the Exchange Act) that is incorporated by reference in this Registration Statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

c. Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, executive officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Commission such indemnification is against public policy as expressed

in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-3 and has duly caused this Amendment No. 1 to Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Monrovia, State of California, on January 9, 2004.

STAAR SURGICAL COMPANY

By: /s/ David Bailey

David Bailey
President, Chief Executive Officer, Chairman and Director (Principal Executive Officer)

Pursuant to the requirements of the Securities Act, this Registration Statement has been signed below by the following persons in the capacities and on the dates indicated.

Signature	Title	
/s/ David Bailey --- David Bailey	President, Chief Executive Officer, Chairman and Director (Principal Executive Officer)	Januar
/s/ John Bily --- John Bily	Chief Financial Officer and Chief Accounting Officer (Principal Financial and Accounting Officer)	Januar
/s/ Donald Duffy* ---	Director	Januar

Donald Duffy		
/s/ Dr. Volker D. Anhaeusser*	Director	Januar
Dr. Volker D. Anhaeusser		
/s/ John R. Gilbert*	Director	Januar
John R. Gilbert		
/s/ David Morrison*	Director	Januar
David Morrison		

*By: /s/ John Bily
John Bily
Attorney-in-Fact
January 9, 2004

EXHIBIT INDEX

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