

STAAR SURGICAL COMPANY
Form 10-K/A
November 20, 2003

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K/A
Amendment No. 3

(Mark One)

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended January 3, 2003

or

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission file number: 0-11634

STAAR SURGICAL COMPANY

Edgar Filing: STAAR SURGICAL COMPANY - Form 10-K/A

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

95-3797439
(I.R.S. Employer
Identification No.)

1911 Walker Avenue
Monrovia, California
(Address of principal executive offices)

91016
(Zip Code)

(626) 303-7902

(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

None

Securities registered pursuant to section 12(g) of the Act:

Common Stock, \$.01 Par Value

(Title of class)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405 of this Chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Act). Yes No

The aggregate market value of the voting and non-voting stock held by non-affiliates of the registrant as of June 28, 2002 was approximately \$69,658,578 based upon the closing price per share of the Common Stock of \$4.120 on that date.

The number of shares outstanding of the registrant's Common Stock as of November 18, 2003 was 18,396,123.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement relating to its 2003 annual meeting of stockholders, which will be filed with the Securities and Exchange Commission pursuant to Regulation 14A within 120 days of the close of the registrant's last fiscal year, are incorporated by reference into Part III of this report.

EXPLANATORY NOTE

STAAR Surgical Company (the Company) is filing this Amendment No. 3 to its Annual Report on Form 10-K for the period ended January 3, 2003 (the Report) to restate its financial statements for the years ended January 4, 2003, December 28, 2001 and December 29, 2000, as more fully discussed in Note 19 of the notes to the financial statements. This Amendment No. 3 corrects the Company's year-end financial statements to include accrued interest income on notes receivable of officers and directors.

To make these corrections and related changes, the Company is amending and restating the following:

the description under the caption "2002 Financial and Other Information Highlights" in Item 1. Business;

Item 6. Selected Financial Data;

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations; and

the Consolidated Financial Statements of the Company included with this Report, including the Notes thereto.

Pursuant to Rule 12b-15, the Company is also including currently dated certifications of the Chief Executive Officer and Chief Financial Officer. While the remainder of the Report is unchanged, the Company is reproducing the Report in its entirety to provide a complete presentation to the reader. This Amendment No. 3 speaks as of the original date of the filing date of the Report, except for certifications, which speak as of their respective dates and the filing date of this Amendment No. 3. Except as specifically indicated, the Report has not been updated to reflect events occurring subsequently to the original filing date.

PART I

This Annual Report on Form 10-K contains statements which constitute forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. These statements include comments regarding the intent, belief or current expectations of the Company and its management. Prospective investors are cautioned that any such forward-looking statements are not guarantees of future performance and involve risks and uncertainties, and that actual results may differ materially from those projected in the forward-looking statements. See Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations Factors That May Affect Future Results.

ITEM 1. BUSINESS

STAAR Surgical Company was incorporated in California in 1982 as a successor to a partnership that was created for the purpose of developing, producing, and marketing Intraocular Lenses (IOLs) and other products for minimally invasive ophthalmic surgery. We reincorporated in Delaware in April 1986. We have evolved to become a developer, manufacturer and global distributor of products used by ophthalmologists and other eye care professionals to improve or correct vision in patients with refractive conditions, cataracts and glaucoma. Unless the context indicates otherwise, when this document refers to we, us or the Company, it is referring to STAAR Surgical Company and its consolidated

subsidiaries.

STAAR operates in three business segments all within ophthalmology: cataract surgery, glaucoma surgery and most important for the Company's future, refractive surgery. Our overall mission is to develop, manufacture and market high margin visual implants that improve a patient's quality of vision.

Refractive Surgery. In the area of refractive surgery, the Company has used its uniquely biocompatible Collamer material to develop and manufacture the Implantable Contact Lens (ICL) and the Toric Implantable Contact Lens (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. The Company's goal is to establish the custom made ICL and TICL as the next paradigm shift in refractive surgery, making the products the dominant revenue generators for the Company over the next four to five years.

Cataract Surgery. Initially, the Company's main product was foldable implants for use after small incision cataract extraction. Since that time we have expanded our range of products for use during cataract surgery to include silicone and Collamer lenses to treat spherical and astigmatic abnormalities, STAARVISC II, a viscoelastic material, the SonicWAVE Phacoemulsification System having unique low energy and high vacuum characteristics and UltraVac VI tubing for use with certain Venturi-type Phacoemulsification machines. This gives us a rounded portfolio of products to meet the needs of the cataract surgeon. Currently, the majority of revenues are generated from these products.

Glaucoma Surgery. For use in glaucoma surgery, the Company developed the AquaFlow Collagen Glaucoma Drainage Device (the AquaFlow Device), an alternative to current methods of treating open angle glaucoma and received FDA approval of the device in July 2000. The AquaFlow Device is implanted in the eye using a minimally invasive procedure for the purpose of reducing intraocular pressure.

Within each of these segments, the Company also sells other instruments, devices and equipment that we manufacture or that are manufactured by others in the ophthalmic industry. In general, such products complement STAAR's proprietary product range and allow us to compete more effectively.

Strategy

The Company has spent the past two years strengthening and improving the organization. This was achieved through the execution of a series of key strategies that included:

Strengthening management at both the Executive and Board levels

Improving cash flow

Reducing costs

Improving gross margins

Closing unprofitable subsidiaries

Settling multiple lawsuits

With a strong foundation firmly in place, the Company can focus on the strategies that are the future of the Company and will provide maximum stockholder value. Those strategies include:

Obtaining U.S. FDA approval of the ICL

Obtaining approvals for the ICL in key new international markets

Improving lens insertion technology which will allow the Company to expand its U.S. customer base for IOLs

Growing the market for the Company's AquaFlow Device

Developing and introducing effective marketing strategies

Strengthening global training programs which form the basis of new product introductions and physician acceptance

2002 Financial and Other Information Highlights

In August 2002, STAAR continued to strengthen its senior management with the appointment of Nick Curtis, Senior Vice President of Sales and Marketing.

The Company continued to strengthen its Board of Directors with the appointment of Don Duffy, retired Chief Financial Officer of Johnson & Johnson's former ophthalmic affiliate, Iolab, to the Board as Chair of the Board's Audit Committee and designated financial expert.

The Company finalized the closure of subsidiaries in Canada and South Africa.

Other charges of \$1.5 million were recorded related to the recognition of deferred losses resulting from the translation of foreign currency statements into U.S. dollars for subsidiaries that were closed, and employee severance costs.

The Company continued its cost containment efforts during 2002 reducing sales and marketing expenses by \$3.2 million. \$1.7 million of the reduction was realized in the U.S. due to overall expense reductions and \$1.5 million of the reduction was primarily the result of subsidiaries that were closed during 2002 and 2001.

The Company recorded a valuation allowance of \$9.0 million against its deferred tax assets in the fourth quarter of 2002. This non-cash charge increased the valuation allowance which now fully reserves the value of the deferred tax assets on the Company's balance sheet.

The Company and John R. Wolf, its former Chief Executive Officer, settled all legal actions between them as memorialized in a Settlement Agreement and Mutual General Release dated November 12, 2002.

The Company acquired the remaining 20% of its German subsidiary in a cashless transaction involving the transfer of share ownership in exchange for the cancellation of outstanding loans owed to the Company.

Revenues for 2002 were \$48.2 million, a decrease of \$2.5 million, or 5%, from 2001. Net loss for 2002 amounted to \$16.8 million, or \$.98 per share, compared to a net loss of \$15.0 million, or \$0.88 per share, reported in 2001. Significant operational matters that affected net earnings for 2002 included non-recurring charges totaling \$1.5 million and a \$9.0 million valuation allowance recorded against the Company's deferred tax assets. Excluding the impact of these charges, the net loss for 2002 was \$6.3 million or \$0.37 per share, compared to the \$4.6 million net loss, or \$0.27 per share, reported for 2001.

Financial Information about Industry Segments

Beginning in 1998, the Company expanded its marketing focus beyond the cataract surgery segment to include the refractive and glaucoma markets. However, during 2002 the cataract segment accounted for approximately 95% of the Company's revenues and thus, the Company operates as one business segment for financial reporting purposes. See Note 15 to the Consolidated Financial Statements for the geographic distribution of the Company's products.

Background

The human eye is a specialized sensory organ capable of receiving visual images that are transmitted to the visual center in the brain. The main parts of the eye are the cornea, the iris, the lens, the retina, and the trabecular meshwork. The cornea is the clear window in the front of the eye through which light passes. The iris is a muscular curtain located behind the cornea which opens and closes to regulate the amount of light entering the eye through the pupil, an opening at the center of the iris. The lens is a clear structure located behind the iris that changes shape to better focus light to the retina, located in the back of the eye. The retina is a layer of nerve tissue consisting of millions of light receptors called rods and cones, which receive the light image and transmit it to the brain via the optic nerve. The anterior chamber of the eye, located in front of the iris, is filled with a watery fluid called the aqueous humour, while the portion of the eye behind the lens is filled with a jelly-like material

Edgar Filing: STAAR SURGICAL COMPANY - Form 10-K/A

called the vitreous humour. The trabecular meshwork, a drainage channel located between the cornea and the surrounding white portion of the eye, maintains a normal pressure in the anterior chamber of the eye by draining excess aqueous humour.

The eye can be affected by common visual defects, disease and/or trauma. The most prevalent ocular diseases are cataracts and glaucoma. Cataract formation is generally an age related situation that involves the hardening and loss of transparency of the natural crystalline lens, impairing visual acuity.

Glaucoma is a progressive ocular disease that manifests itself through increased intraocular pressure. This, in turn, results in a decrease of the visual field and damage to the optic disc. Untreated, glaucoma can result in blindness.

Refractive disorders include myopia, hyperopia, astigmatism and presbyopia. Myopia and hyperopia are caused by either flat or overly curved corneas which result in improper focusing of light on the retina. They are also known as near-sightedness and far-sightedness, respectively. Astigmatism is characterized by an irregularly shaped cornea resulting in blurred vision. Presbyopia is an age related condition caused by the loss of elasticity of the natural crystalline lens, reducing the eye's ability to accommodate or adjust for varying distances.

Industry

According to industry analysts, the global market for ophthalmic surgery products is approximately \$3.5 billion worldwide. The major factors influencing this market are:

the introduction of new methods of correcting vision problems and advances in medical technology,

an aging worldwide population,

the importance of reimbursement, both government and private, and

the growing importance of international markets.

Our products serve the following sectors of the ophthalmic market.

Cataract Treatment. The occurrence of cataracts is directly associated with the aging process. Favorable demographics indicate that the number of Americans older than 65 has increased tenfold since 1900, and according to the U.S. Census Bureau, currently represent approximately 13% of the total population. A cataract usually results from the slow opacification of the crystalline lens, resulting in reduced vision. Once past the age of 65, 50% of the population develops cataracts. Cataract extractions are accompanied by the insertion of an IOL. Industry sources estimate that approximately 2.4 million IOLs were implanted in the United States in 2002, generating approximately \$260 million in sales. We believe that a similar number of IOLs were implanted outside the United States (excluding China and Russia, for which no reliable data exists), generating an additional \$250 million in sales. We believe that approximately 90% of the domestic market for IOLs in 2002 was held by foldable IOLs, compared to approximately 15% in 1992, and that approximately 60% of the international market share is presently held by foldable IOLs. We believe the share of the worldwide market held by foldable IOLs will continue to increase due to the benefits of foldable IOLs over non-foldable IOLs.

Edgar Filing: STAAR SURGICAL COMPANY - Form 10-K/A

Glaucoma Treatment. The treatment for glaucoma encompasses drug therapies as well as traditional and laser surgical procedures. There is no known cure for glaucoma. The most commonly prescribed glaucoma drugs either inhibit the production of intraocular fluid or promote increased drainage of intraocular fluid, in either case reducing intraocular pressure and the potential for optic nerve damage. Traditional surgical procedures for glaucoma (trabeculectomies and shunts) and laser surgical procedures for glaucoma (trabeculoplasties) remove a portion of the trabecular meshwork to create a channel for fluid to drain from the eye. The selection of drug treatment over a surgical or laser procedure is, in part, dependent upon the stage of the disease and the prevailing glaucoma treatment used in the country in which the treatment is prescribed.

While we believe that glaucoma currently afflicts approximately 2 million persons in the U.S., only about 50% of those persons have actually been diagnosed with the disease. Industry analysts estimate that approximately 67 million people worldwide have glaucoma. The worldwide market for glaucoma drugs is

approximately \$2 billion. We estimate that 125,000 conventional surgical procedures and 250,000 laser surgeries were performed in the U.S. alone in 2000, which we believe represents total expenditures of approximately \$750 million.

Glaucoma drugs are prescribed for patients to control the production of intraocular fluid and the corresponding increase in intraocular pressure. In some cases, patients build up a tolerance to the medications and they must be changed or combined to improve response. Patients may experience side effects that range from burning and stinging eyes to allergies or more serious systemic problems. For many patients, the symptoms of glaucoma are not readily apparent, which may cause the patients to fail to adhere to the drug regimen.

Conventional surgical and laser procedures for glaucoma create a channel for fluid to drain from the eye. According to one study, conventional and laser surgery for glaucoma has an estimated initial success rate within one to two years of only 70% to 80%, with the success rate decreasing to 46% within five years.

Refractive Vision Correction. It is estimated that 52% of the U.S. population or 162 million people are in need of some form of vision correction. Of this group, the Company's target market has been defined as those people between 18 and 55 years of age and within a socioeconomic bracket where elective surgery is affordable. The target market is estimated at 54.4 million people. Of the target market, approximately 3 million people (5.4%) have severe myopia (which is defined as greater than 7.5 diopters) and approximately 4.6 million people (8.4%) have moderate myopia (which is defined from 4.0 to 7.0 diopters). Approximately 1.6 million people have severe hyperopia (which is defined as greater than 3.0 diopters). In addition, it is estimated that 20% of the total population has some form of astigmatism, although in the Company's target population, the percentage of those with astigmatism is believed to be significantly higher than in the general population. The market outside the U.S. is larger than the U.S. market. It is estimated that approximately 50% of the world's population needs some form of vision correction.

In the U.S., refractive surgery volumes have declined approximately 1% in 2002 (1.316 million procedures) over 2001 (1.324 million procedures). This downward trend is expected to improve in 2003 as wavefront technology is introduced thereby re-energizing the laser vision correction market. SG Cowan estimates a 14% growth rate in domestic refractive procedures as improved technologies generate renewed interest in quality of vision.

We believe that this focus on improvement in quality of vision will provide the perfect atmosphere for the introduction of phakic IOLs as the quality of vision with these lenses is superior to laser vision correction.

Principal Products

Our products are designed to:

Improve patient outcomes,

Minimize patient risk and discomfort, and

Simplify ophthalmic procedures and/or post-operative care for the surgeon and the patient.

We sell our products worldwide, principally to ophthalmologists, surgical centers, hospitals, managed care providers, health maintenance organizations, group purchasing organizations and government facilities. Demand for our products is not seasonal.

Intraocular Lenses (IOLs) and Related Cataract Treatment Products. We produce and market a line of foldable IOLs for use in minimally invasive cataract surgical procedures. Our IOLs can be folded or otherwise deformed, and therefore can be implanted into the eye through an incision as small as 2.65 mm. Once inserted, the IOL unfolds naturally into the capsular bag that previously held the cataractous lens.

Our foldable IOLs are manufactured from both our proprietary Collamer material and silicone. Both materials are offered in two differently configured styles, the single-piece plate haptic design and the three-piece design where the optic is combined with polyimide loop haptics. During 2001, the Company recalled its three-piece Collamer lens. The Company reintroduced the lens in September 2002. The selection of one style over the other is primarily based on the preference of the ophthalmologist. Sales of foldable IOLs accounted for approximately 66% of our total revenues for the 2002 fiscal year, 73% of total revenues for the 2001 fiscal year and approximately 69% of total revenues for the 2000 fiscal year.

We have developed and currently market globally the Toric IOL, a toric version of our single-piece silicone IOL, which is specifically designed for patients with pre-existing astigmatism. The Toric IOL is the only IOL that has FDA approval to include in its labeling that it improves uncorrected visual acuity. The Toric IOL is the first refractive product we offered in the U.S., and is a significant addition to our line of cataract products. In May 2000, the Health Care Financing Administration, now known as the Centers for Medicare and Medicaid (CMS), granted our application to have the Toric IOL designated as a new technology. The new technology designation allows ambulatory surgical centers to receive an additional \$50 per lens above the standard Medicare reimbursement rate through May 2005. Furthermore, CMS granted our application for pass-through status for our Toric IOL which, until April 1, 2002, allows hospitals to pay us our list price for the lenses and pass through the total amount to CMS for reimbursement. Pass-through status may last for a period of two to three years, although re-evaluation and adjustment is possible in January of each year. The adjustment announced for 2002 significantly changes the impact of pass-through status in that it reimburses only a percentage of the invoiced amount. We anticipate that this change may have a negative effect on the pricing of our Toric IOLs to hospitals, although the full impact of the adjustment will not be known until the final regulations are issued.

In April 2000, we received approval from the FDA for our single-piece Collamer IOL for cataract surgery, allowing us to market the lens throughout the United States. The Collamer IOL was approved for use in Canada and the European Union during 1999. We believe that the Collamer material, which is a biomaterial, is superior to other materials used in the manufacture of IOLs in the marketplace because collagen is incorporated into it.

Phacoemulsification (phaco) machines are used during cataract surgery to remove the patient's cataractous lens, usually through a small incision. The most desired equipment will improve surgical outcomes and make cataract surgery simpler for the physician and safer for the patient. There are approximately 1,000 to 1,500 phaco machines sold annually at prices ranging from \$20,000 to \$85,000. The market for this equipment ranges from \$50 million to \$100 million annually and the market for accessories such as hand pieces, surgical packs, and phaco tips ranges from \$50 million to \$75 million annually. During 1998 we introduced the WAVE Phacoemulsification Machine, the precursor to our SonicWAVE Phacoemulsification System, launched in October 2000, which we believe represents the next generation of this product. The SonicWAVE Phacoemulsification System offers physicians the ability to use standard ultrasound as well as sonic technology, which removes cataract material by using low frequency sonic pulses. Sonic pulses avoid the generation of heat at the surgery site, thereby reducing the risk of burns to the cornea. The SonicWAVE Phacoemulsification System has 510(k) approval. We received CE Mark in April 2001, allowing us to sell in the European community and began international shipments of this product on April 16, 2001.

In August 2001 the Company entered into an agreement with Surgin Surgical Instruments, Inc. to distribute UltraVac V1 phaco packs for certain Venturi-type phaco systems. The UltraVac V1 coiled tubing allows surgeons to operate more efficiently at potentially higher levels of vacuum with the assurance of greater anterior chamber stability.

As part of our approach to providing a complete line of complementary products for use in minimally invasive cataract surgery, we also market several styles of lens injectors and sterile cartridges used to insert our IOLs and several styles of disposable and reusable surgical packs and ultrasonic cutting tips to be used with the SonicWAVE Phacoemulsification System.

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

We believe that the compatibility of the human eye with the material from which the AquaFlow Device is made and the minimally invasive nature of the surgery offer several advantages over existing surgical procedures, including:

reduced risk of surgical complications compared to trabeculectomy,

a longer-term solution than medications,

predictable outcomes, making case management easier and less time consuming,

less need for pressure-reducing medications,

enabling the patient to have minimally invasive laser surgery if further pressure reduction becomes necessary over the long term, and

cost effectiveness compared to surgical and medication alternatives.

We believe the AquaFlow Device is an attractive product for:

ophthalmic surgeons who have traditionally referred their patients to glaucoma specialists;

managed care and health maintenance organizations and group purchasing organizations that desire to control their costs and at the same time provide their customers with a higher standard of health care; and

less developed countries which lack the resources and infrastructure to provide the continuous treatments mandated by drug therapy.

While we believe this market is very conservative, there is a continuing interest in learning the surgical procedure to implant the AquaFlow Device. Adoption by ophthalmic surgeons, however, will be dependent upon the rate at which they learn to perform the surgical procedure or the development of instrumentation to simplify the procedure. Our trained technical sales staff and several surgical specialists educate surgeons on implanting the AquaFlow Device. We have also established regional Centers of Excellence, where surgeons are successfully implanting the AquaFlow Device, to assist in training new surgeons and in promoting the product.

Edgar Filing: STAAR SURGICAL COMPANY - Form 10-K/A

We introduced the AquaFlow Device in late 1995 for commercial sale on a limited basis in South Africa and selected countries in Europe and South America. In August 1997, we received CE Mark for the AquaFlow Device, allowing us to sell it in each of the countries comprising the European Union. In January 2000, the Canadian government, through Health Canada, issued a Medical Device License, allowing us to sell the AquaFlow Device in Canada. In July 2001, we received pre-market approval for the AquaFlow Device from the FDA.

Refractive Correction Implantable Contact Lenses (ICLs). ICLs are lenses implanted into the eye in order to correct refractive disorders such as myopia, hyperopia and astigmatism. The ICL is capable of correcting a wide range of refractive disorders from low to severe conditions.

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

We believe the use of an ICL will afford a number of advantages over existing refractive surgical procedures, because:

The ICL provides superior quality of vision compared to currently available refractive procedures.

The ICL provides superior predictability of surgical outcomes.

The ICL can correct significantly greater levels of myopia, hyperopia and astigmatism than other procedures.

The ICL decreases the risk of loss of best corrected vision as a result of complications.

The ICL can correct or improve other vision problems, such as amblyopia (lazy eye) and keratoconus (a condition causing marked astigmatism) and provide an alternative to corneal refractive surgery.

The ICL is implanted through an astigmatically neutral incision.

The ICL enables faster recovery of vision.

The ICL produces superior optical correction, ensuring clear vision.

We commenced commercial sales of ICLs in late 1996 on a limited basis in South Africa, China, and selected countries in Europe and South America. In August 1997, we received CE Mark allowing us to sell the ICL in each of the countries comprising the European Union. In February 1997, the FDA granted us an investigational device exemption (IDE) to begin clinical studies consisting of three distinct phases within the U.S. We have completed enrollment of Phase III of the IDE clinical trials for the correction of myopia and we are presently engaged in completing enrollment of Phase III of the IDE for the correction of hyperopia. We anticipate filing a pre-market approval application for the ICL correcting myopia in the second quarter of 2003. The ICL received approval in Canada in July 2001 and in Korea in April 2002. The Company has submitted for registration in Taiwan and approval is pending for Australia. The Canon-STAAR Company in Japan will begin clinical trials of the ICL in the second quarter of 2003.

In January 2002, the FDA conditionally approved an IDE for the Toric ICL, allowing us to begin clinical investigation on the lens in the United States with patients having myopia in the range of -3.0 diopters to -20.0 diopters and astigmatism in the range of +1.0 diopters to +4.0 diopters. Enrollment began in August 2002 with six investigational sites. Industry sources estimate 20% of the population requiring vision correction have astigmatism with the percentage higher in severe myopia.

Distribution and Customers

We market our products to a variety of health care providers, including surgical centers, hospitals, managed care providers, health maintenance organizations, group purchasing organizations and government facilities. The primary user of our products is the ophthalmologist. No material part of our business, taken as a whole, is dependant upon a single or a few customers.

STAAR maintains direct distribution in the United States and Canada. Sales efforts are supported through a network of independent manufacturers representatives. The representatives are compensated via commissions

based on annual sales volumes and targets. International sales are conducted through a series of independent distributors.

STAAR supports the efforts of its agents and distributors through the marketing efforts of its internal marketing departments. Sales efforts are supplemented via promotional materials, educational courses, speakers programs and technical presentations.

Sources and Availability of Raw Materials

Our IOLs, ICLs, and our AquaFlow glaucoma devices are manufactured in facilities located in California and Switzerland. Our SonicWAVE Phacoemulsification System is manufactured by our subsidiary, Circuit Tree Medical, Inc., also located in California. The components used in the manufacture of the SonicWAVE System are available from multiple sources.

Manufacturing is currently outsourced for our viscoelastic, custom procedure packs and phaco packs. Many of our raw material components are purchased to our specifications from suppliers. Most of these components are standard parts and available from multiple sources. Although we presently have one supplier for silicone, the principal raw material for our silicone IOL is available from several other sources. We recently validated a new supplier of polypropylene plastic resin for our lens delivery systems which is readily available in the marketplace. The proprietary collagen-based raw material used to manufacture IOLs, ICLs, and the Aqua Flow Device is internally sole-sourced at one of our facilities in California. If the supply of these collagen-based raw materials is interrupted we know of no alternate supplier, and therefore, any such supply interruption could result in our inability to manufacture these products.

Patents, Trademarks and Licenses

We or our licensors have pending patent applications and issued patents in various countries relating specifically to our products or various aspects of them, including our core patent (the Mazzocco Patent) relating to methods of folding or deforming an IOL or ICL for use in minimally invasive surgery. The Mazzocco Patent was granted by the United States Patent Office in March 1986 to Thomas Mazzocco, M.D., who was a practicing ophthalmologist and a co-founder of the Company. The Mazzocco Patent will expire in the year 2003. We do not derive significant revenues from this patent, and we do not believe that its expiration is of material importance in relation to our overall sales. We have also acquired or applied for several patents for insertion devices, glaucoma devices and other products for ophthalmic use.

In May 1995, Intersectional Research and Technology Complex Eye Microsurgery (IRTC) granted an exclusive royalty-bearing license to our subsidiary, STAAR Surgical AG, to manufacture, use and sell IRTC's glaucoma devices in the United States, Europe, Latin America, Africa, and Asia, and non-exclusive rights with respect to the countries in the Commonwealth of Independent States (the former Union of Soviet Socialist Republic) and China. In January 1996, IRTC granted an exclusive royalty bearing license to STAAR Surgical AG to manufacture, use and sell implantable contact lenses using IRTC's biocompatible materials in the United States, Europe, Latin America, Africa, and Asia, and non-exclusive rights with respect to the Commonwealth of Independent States. The terms of these licenses extend for the lives of the patents. In connection with these licenses, IRTC also assigned to us its patent for its biocompatible material, which we use in manufacturing our ICLs and some of our IOLs. We have since adopted IRTC's biocompatible material and glaucoma device design for our AquaFlow Device, and have incorporated IRTC's biocompatible materials for use with our proprietary ICL design. These patents and the technology rights are of material importance to our refractive products market segment. Each of these patents will expire in the year 2009. We are continuing to expand our patent portfolios of refractive and glaucoma products so that we do not become dependent on the protection of any single patent.

In connection with our acquisition of a majority of the outstanding shares of Circuit Tree Medical, Inc., in December 1999, we acquired patents relating to the SonicWAVE Phacoemulsification System and other related technologies.

We have registered the mark STAAR and our associated logo with the United States Patent and Trademark Office. We also have common law trademark rights to other marks and we have applied for registration for some of these marks.

We have granted licenses to certain of our patents, trade secrets and technology, including our foldable technology, to other companies for use in connection with their cataract products. The licenses under the patents extend for the life of the patents. The licensees include Allergan Medical Optics (AMO), Alcon Surgical, Inc. (Alcon), Bausch & Lomb Surgical (Bausch & Lomb), CIBA Vision, Pharmacia & Upjohn, Inc. (Pharmacia & Upjohn) and Canon-STAAR Company, Inc., a joint venture we own with Canon, Inc. and Canon Sales Co., Inc. We licensed certain of our patented foldable technology on an exclusive basis to Canon-STAAR Company, Inc. (for Japan only), on a non-exclusive basis to Alcon, Bausch & Lomb, CIBA Vision and Canon-STAAR Company, Inc. (with respect to the world other than Japan), and on a co-exclusive basis to AMO. At the time these licenses were granted, we received substantial pre-payments of royalties on all but one of the licenses. We expect to receive continuing revenues from only one of these licenses through March 2003. Our business strategy is not dependent upon realizing royalties from these licenses in the future.

Competitive Conditions

Competition in the medical device field is intense and characterized by extensive research and development and rapid technological change. Development by competitors of new or improved products, processes or technologies may make our products obsolete or less competitive. We will be required to devote continued efforts and significant financial resources to enhance our existing products and to develop new products for the ophthalmic industry.

We believe our primary competition in the development and sale of products used to surgically correct cataracts, namely foldable IOLs and phacoemulsification machines, includes Bausch & Lomb, AMO, Alcon, Pharmacia & Upjohn, Inc. and CIBA Vision. Each of these competitors is a licensee of our foldable technology. Significant competitors in the hard IOL market include Bausch & Lomb, AMO, Pharmacia & Upjohn, Inc., Alcon and CIBA Vision. These competitors have been established for longer periods of time than we have and have significantly greater resources than we have, factors that give them the advantages of greater name recognition, larger sales operations and greater ability to finance research and development and proceedings for regulatory approval.

Our primary competition in the development and sale of products used to treat glaucoma is from pharmaceutical companies, primarily because drug therapy is, and for years has been, the accepted treatment for glaucoma. The portion of this market held by medical devices used to treat glaucoma is insignificant at present. We believe that Merck & Company, Inc., Pharmacia, Novartis, Alcon, Allergan and Bausch & Lomb are the largest providers of drugs used to treat glaucoma within the United States, and CIBA Vision Corporation, Pharmacia & Upjohn, Inc. and Lederle Laboratories, a subsidiary of American Home Products, are the largest internationally. There are other devices under development to be used in conjunction with a non-penetrating deep sclerectomy for the surgical management of glaucoma. These devices are manufactured by Alcon, Corneal, Optonol and Glaukos.

Our ICL will face significant competition in the marketplace from products that improve or correct refractive conditions, such as corrective eyeglasses and external contact lenses, and particularly from providers of conventional and laser surgical procedures. These are products long established in the marketplace and familiar to patients in need of refractive correction. Furthermore, corrective eyeglasses and external contact lenses are more easily obtained, in that a prescription is usually written following a routine eye examination in a doctor's office, without admitting the patient to a hospital or surgery center. We believe that the following providers of laser surgical procedures comprise our primary competition in the marketplace for patients requiring refractive corrections: Alcon, Bausch & Lomb, VISX, Nidek and Laser Sight all market Excimer lasers for corneal refractive surgery. The expected approval of custom ablation, along with the addition of wavefront technology,

will increase awareness of corneal refractive surgery by patients and practitioners. Conductive Keratoplasty (CK) by Refractec will compete for the hyperopic market for +1.0 to +3.0 diopters. In the phakic IOL market, the ICL faces Ophtec (to be distributed in the United States by Advanced Medical Optics), Bausch & Lomb and CIBA, all with phakic IOLs under investigation.

Regulatory Requirements

Our products are subject to regulatory approval in the United States and in foreign countries. The following discussion outlines the various kinds of reviews to which our products or production facilities may be subject.

Clinical Regulatory Requirements within the United States. Under the Federal Food, Drug & Cosmetic Act as amended by the Food and Drug Administration Modernization Act of 1997 (The Act), the FDA has the authority to adopt regulations that:

set standards for medical devices,

require proof of safety and effectiveness prior to marketing devices which the FDA believes require pre-market clearance,

require test data approval prior to clinical evaluation of human use,

permit detailed inspections of device manufacturing facilities,

establish good manufacturing practices that must be followed in device manufacture,

require reporting of serious product defects to the FDA, and

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

Most of our products are medical devices intended for human use within the meaning of the Act and are, therefore, subject to FDA regulation.

The FDA establishes complex procedures for compliance based upon regulations that designate devices as Class I (general controls, such as compliance with labeling and record-keeping requirements), Class II (performance standards in addition to general controls) or Class III (pre-market approval application (PMAA) before commercial marketing). Class III devices are the most extensively regulated because the FDA has determined they are life-supporting, are of substantial importance in preventing impairment of health, or present a potential unreasonable risk of illness or injury. The effect of assigning a device to Class III is to require each manufacturer to submit to the FDA a PMAA that includes information on the safety and effectiveness of the device.

Edgar Filing: STAAR SURGICAL COMPANY - Form 10-K/A

A medical device that is substantially equivalent to a directly related medical device previously in commerce may be eligible for the FDA's abbreviated pre-market notification 510(k) review process. FDA 510(k) clearance is a grandfather process. As such, FDA clearance does not imply that the safety, reliability and effectiveness of the medical device has been approved or validated by the FDA, but merely means that the medical device is substantially equivalent to a previously cleared commercially-related medical device. The review period and FDA determination as to substantial equivalence should be made within 90 days of submission of a 510(k) application, unless additional information or clarification or clinical studies are requested or required by the FDA. As a practical matter, the review process and FDA determination may take longer than 90 days.

Our IOLs and ICLs are Class III devices, and our AquaFlow Devices, lens injectors, phacoemulsification equipment, ultrasonic cutting tips and surgical packs are Class II devices. We have received FDA pre-market approval for our IOLs (including the Toric and the Collamer IOLs) and AquaFlow Device and FDA 510(k)

clearance for our phacoemulsification equipment, lens injectors, ultrasonic cutting tips and surgical packs. We have completed the enrollment for Phase III of the clinical study of the ICL that corrects myopia and we continue to enroll patients in Phase III of the clinical study of the ICL that corrects hyperopia. In September 2001, we applied for an investigation device exemption (IDE) for a toric version of the ICL. In January 2002, the FDA conditionally approved an IDE for the Toric ICL. We expect to submit an application to the FDA for pre-market approval of our ICL to correct myopia in the second quarter of 2003.

As a manufacturer of medical devices, our manufacturing processes and facilities are subject to continuing review by the FDA and various state agencies to ensure compliance with good manufacturing practices. These agencies inspect our facilities from time to time to determine whether we are in compliance with various regulations relating to manufacturing practices, validation, testing, quality control and product labeling.

We are also subject to regulation by the local Air Pollution Control District and the United States Environmental Protection Agency as a result of some of the chemicals used in our manufacturing processes.

Medical device laws and regulations similar to those described above are also in effect in some of the countries to which we export our products. These range from comprehensive device approval requirements for some or all of our medical device products to requests for product data or certifications.

Clinical Regulatory Requirements In Foreign Countries. There is a wide variation in the approval or clearance requirements necessary to market products in foreign countries. The requirements range from minimal requirements to a level comparable to the FDA. For example, many countries in South America have minimal regulatory requirements, while many developed countries, such as Japan, have requirements at least as stringent as those of the FDA. FDA acceptance is not always a substitute for foreign government approval or clearance.

As of June 1998, the member countries of the European Union (the Union) require that all medical products sold within their borders carry a Conformance Europeene Mark (CE Mark). The CE Mark denotes that the applicable medical device has been found to be in compliance with guidelines concerning manufacturing and quality control, technical specifications and biological or chemical and clinical safety. The CE Mark supersedes all current medical device regulatory requirements for Union countries. We have obtained the CE Mark for all of our principal products including our ICL and TICL, IOLs (including the Toric IOL and Collamer IOL), SonicWAVE Phacoemulsification System and our AquaFlow Device.

Other Regulatory Requirements. Sales of our products may be affected by health care reimbursement practices. For example, in January 1994, the Health Care Financing Administration adopted rules that limit Medicare reimbursement for IOLs implanted in Medicare patients to a flat fee of \$150.

We are also subject to various federal, state and local laws applicable to our operations including, among other things, working conditions, laboratory and manufacturing practices, and the use and disposal of hazardous or potentially hazardous substances.

Research and Development

We are focused on furthering technological advancements in the ophthalmic products industry through continuous innovative development of ophthalmic products and materials and related surgical techniques. We maintain an active internal research and development program which

Edgar Filing: STAAR SURGICAL COMPANY - Form 10-K/A

activities includes research and development, clinical, and regulatory affairs and is comprised of 28 employees. Over the past year, we have principally focused our research and development efforts on:

developing our Toric ICL, and developing new material IOLs (including a reintroduction of the three-piece Collamer IOL in the U.S.) and ICLs for the correction of presbyopia,

improving insertion and delivery systems for our foldable products, including a successful design and launch of the environmentally controlled cartridge,

generally improving the manufacturing systems and procedures for all products to reduce manufacturing costs resulting in yield increases for Collamer products in 2002,

improving the SonicWAVE Phacoemulsification System and obtaining FDA 510(k) approval for the Cruise Control device, and

developing products and extending foreign registrations for the refractive market.

Research and development expenses were approximately \$4,016,000, \$3,800,000, and \$4,215,000 for our 2002, 2001 and 2000 fiscal years, respectively.

Environmental Matters

The Company is subject to federal, state, local and foreign environmental laws and regulations. We believe that our operations comply in all material respects with applicable environmental laws and regulations in each country where we have a business presence. We do not anticipate that compliance with these laws will have any material impact on our capital expenditures, earnings or competitive position. We currently have no plans to invest in material capital expenditures for environmental control facilities for the remainder of our current fiscal year or for the next fiscal year. We are not aware of any pending litigation or significant financial obligations arising from current or past environmental practices that are likely to have a material adverse impact on our financial position. However, environmental problems relating to our properties could develop in the future, and such problems could require significant expenditures. Additionally, we are unable to predict changes in legislation or regulations that may be adopted or enacted in the future and that may adversely affect us.

Significant Subsidiaries

The Company's only significant subsidiary is STAAR Surgical AG, a wholly owned entity incorporated in Switzerland. This subsidiary develops, manufactures and distributes products worldwide including Collamer IOLs, ICLs and the AquaFlow Device. STAAR Surgical AG also controls 100% of Domilens GMBH, a European sales subsidiary that distributes both STAAR products and products from various competitors.

Employees

Together with our subsidiaries, we had a total of 237 employees as of February 18, 2003, including 36 in administration, 78 in marketing and sales, 28 in research and development and technical services and 95 in manufacturing, quality control and shipping.

Financial Information about Foreign and Domestic Operations

Approximately \$24,450,000, \$27,558,000 and \$30,986,000 of our overall revenues were generated in the United States for the 2002, 2001 and 2000 fiscal years, respectively, constituting approximately 51%, 54% and 57% of overall revenues for those years. We believe that international markets represent a significant opportunity for continued growth. Europe, which is our principal foreign market, generated approximately

Edgar Filing: STAAR SURGICAL COMPANY - Form 10-K/A

\$19,409,000, \$19,572,000 and \$19,101,000 in revenues for the 2002, 2001 and 2000 fiscal years, respectively, constituting approximately 40%, 39% and 35% of overall revenues for those fiscal years. The remaining foreign sales were attributed to the Canadian, Asian/Pacific, South African, Australian and South American geographic areas. Most all products sold in 2002 were manufactured in the United States and Switzerland. See Note 15 to the Consolidated Financial Statements.

A significant portion of our revenues relate to our international sales and operations. We expect this to continue to be the case in the future. Our international sales and operations subject us to several potential risks, including:

loss of distribution of third-party lines,

risks associated with fluctuating exchange rates,

the regulation of fund transfers by foreign governments,

United States and foreign export and import duties and tariffs, and

political instability.

The occurrence of any of the foregoing could materially and adversely affect our business. We have not previously engaged in activities to mitigate the effects of foreign currency fluctuations, because historically we have been generally paid in U.S. dollars with respect to our international operations. As earnings from international operations increase, our exposure to fluctuations in foreign currencies may increase, and we may utilize forward exchange rate contracts or engage in other efforts to mitigate foreign currency risks.

Although our continued growth is in part dependent on the expansion of international sales of our products, this expansion will involve operations in markets where we may not be experienced. We may not be successful in capturing a significant portion of these markets for many reasons, including unsuccessful distribution efforts and an inability to obtain regulatory approvals.

Additional Information

During the second quarter of 2003, the Company expects to make available free of charge through its website, *www.staar.com*, its Annual Report on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) of the Securities Exchange Act of 1934, as soon as reasonably practicable after those reports are filed with the Securities and Exchange Commission.

ITEM 2. PROPERTIES

Our operations are conducted in leased facilities throughout the world. Our executive offices, manufacturing, warehouse and distribution, and primary research facilities are located in Monrovia, California. STAAR Surgical AG maintains office, manufacturing, warehouse and distribution, and research facilities in Nidau, Switzerland. The Company has two additional facilities in California, one for raw material support and another for research and manufacturing. Outside the United States, the Company leases facilities in Germany, Australia, Switzerland, France, and Austria. The Company will exit its France facility in 2003. We believe our manufacturing facilities in the U.S. and Switzerland are suitable and adequate for our current and future planned requirements since manufacturing runs only one shift. However, the Company is at capacity in the U.S. and Switzerland in the areas of distribution and administration. The Company would require additional space to support growth in those areas, although this is not anticipated for 2003.

ITEM 3. LEGAL PROCEEDINGS

We are party to various claims and legal proceedings arising out of the normal course of our business. These claims and legal proceedings relate to contractual rights and obligations, employment matters, and claims of product liability. In addition to legal proceedings arising out of the

Edgar Filing: STAAR SURGICAL COMPANY - Form 10-K/A

normal course of our business, on January 3, 2003 we were named as a party in the following pending actions.

Mario Pelegrina v. Andrew F. Pollet, John R. Wolf, Peter J. Utrata, Volker D. Anhaeusser, Joseph Priske, William Huddleston, Carl Manisco, individuals, Pollet & Richardson, a California corporation, and Iotech, Inc., a California corporation, Defendants, and STAAR Surgical Company, Nominal Defendant, Court of Chancery of the State of Delaware, Case No. 18556. In December 2000, Mario Pelegrina filed this shareholder derivative suit against us and certain named directors and officers. Mr. Pelegrina alleges that these directors and officers breached their fiduciary duties by engaging in self-dealing and waste of our assets. Because this is a shareholder

derivative action, we are a putative plaintiff and stand to receive any damages that may be awarded. Mr. Pelegrina took no steps to prosecute the action until May 2002, when the Court of Chancery requested a status report on the litigation. On October 9, 2002, we filed a motion to dismiss the action and began preparing a brief in support of the motion. The briefing has been stayed since December 2002, with Mr. Pelegrina's consent, to enable us to discuss a potential voluntary dismissal of the action.

Richard Leza v. STAAR Surgical Company, Pollet & Richardson, Los Angeles Superior Court, Case Number BC257159: This action was filed on August 30, 2001. Plaintiff Richard Leza was the Company's former Vice President of Finance, Business Development and Corporate Strategy. He was terminated on November 1, 2000. Mr. Leza alleged that no cause existed for his termination, that he was entitled to acceleration of an option to purchase 50,000 shares of the Company's Common Stock, that a loan in the amount of \$120,000 made to him by the Company should have been forgiven, and that he is entitled to a severance payment of \$130,000. Mr. Leza also alleged that the Company breached the implied covenant of good faith and fair dealing and terminated him in violation of public policy. On February 27, 2003, the Company and Mr. Leza settled their disputes. Pursuant to the settlement, the Company agreed to pay Mr. Leza monthly payments totaling \$180,000 over a 15-month period. The Company also agreed to issue Mr. Leza an option to purchase 75,000 shares of the Company's Common Stock and forgave a note receivable of \$120,000.

John R. Wolf v. STAAR Surgical Company, Los Angeles Superior Court; Case No. BC235396. On November 12, 2002, the Company and its former Chief Executive Officer, John R. Wolf, settled their disputes resulting in the dismissal of all legal actions between them. The settlement provided for completion of Mr. Wolf's transfer of 243,000 shares of the Company's Common Stock pursuant to the Form 4 executed May 9, 2000, in satisfaction of \$2.1 million in promissory notes executed by Mr. Wolf in favor of the Company.

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

There were no matters submitted to a vote of security holders during the quarter ended January 3, 2003.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY AND RELATED STOCKHOLDER MATTERS

Our Common Stock is quoted on the National Association of Securities Dealers Automatic Quotation System National Market under the symbol STAA. The following table sets forth the reported high and low bid prices of the Common Stock as reported by NASDAQ for the calendar periods indicated:

| <u>Period</u> | <u>High</u> | <u>Low</u> |
|---------------------------------------|-------------|------------|
| 2003 | | |
| First Quarter (through April 1, 2003) | \$ 6.550 | \$ 3.050 |
| 2002 | | |
| Fourth Quarter | \$ 4.580 | \$ 2.100 |
| Third Quarter | 4.200 | 1.710 |
| Second Quarter | 6.020 | 3.750 |
| First Quarter | 5.440 | 3.500 |
| 2001 | | |
| Fourth Quarter | \$ 4.250 | \$ 1.700 |
| Third Quarter | 5.250 | 1.550 |
| Second Quarter | 5.500 | 2.000 |
| First Quarter | 13.875 | 3.563 |

On April 1, 2003, the closing price of the Company's Common Stock was \$5.95. Stockholders are urged to obtain current market quotations for the Common Stock.

As of March 13, 2003, there were approximately 615 record holders of our Common Stock.

We have not paid any cash dividends on our Common Stock since our inception. We currently anticipate that any earnings will be retained to further develop our business and that no cash dividends on the Common Stock will be declared in the foreseeable future. Furthermore, pursuant to its domestic credit facility, the Company cannot declare or pay any dividend to its stockholders. The declaration and payment of any such dividends in the future would not only be subject to approval by the Company's lender, but would also depend upon the Company's earnings, financial condition, capital needs and other factors deemed relevant by the Board of Directors.

During the three years ended December 31, 2002, the Company issued an aggregate of 191,766 shares of Common Stock (the "Shares") without registration under the Securities Act of 1933, as amended (the "Act"), to 8 directors, officers, employees and consultants (the "Participants") under its 1996 STAAR Surgical Company Stock Option Plan and 1998 STAAR Surgical Company Stock Option Plan (the "Plans") for an aggregate cash consideration of \$1,650,955. The Company sold the Shares directly, without the services of an underwriter, in reliance upon Rule 506 of Regulation D promulgated under Section 4(2) of the Act. The Company believes that each Participant who purchased Shares was an accredited investor within the meaning of Regulation D.

During such three year period, granted but unexercised options (the "Options") to purchase shares of the Company's Common Stock without registration under the Act totaled 1,823,298 to 49 Participants under the Plans. The average exercise price of the Options is \$7.15, and the Options become exercisable in installments. As of April 1, 2003, Options to purchase 1,198,457 shares of Common Stock were exercisable. The

Edgar Filing: STAAR SURGICAL COMPANY - Form 10-K/A

Company granted the Options directly, without the services of an underwriter. No Options have been exercised, and the Company intends to register under the Act the shares of Common Stock issuable upon exercise of the Options before the exercise thereof.

ITEM 6. SELECTED FINANCIAL DATA

The following table sets forth selected consolidated financial data with respect to the five most recent fiscal years ended January 3, 2003, December 28, 2001, December 29, 2000, December 31, 1999, and January 1, 1999. The selected consolidated statement of income data set forth below for each of the three most recent fiscal years, and the selected consolidated balance sheet data set forth below at January 3, 2003 and December 28, 2001, are derived from the Consolidated Financial Statements which have been audited by BDO Seidman, LLP, independent certified public accountants, as indicated in their report which is included elsewhere in this Annual Report. The selected consolidated statement of income data set forth below for each of the two fiscal years in the periods ended December 31, 1999 and January 1, 1999, and the consolidated balance sheet data set forth below at December 29, 2000, December 31, 1999, and January 1, 1999 are derived from the Company's audited consolidated financial statements not included in this Annual Report. The selected consolidated financial data should be read in conjunction with the Consolidated Financial Statements of the Company, and the Notes thereto, included elsewhere in this Annual Report, and Management's Discussion and Analysis of Financial Condition and Results of Operations in Item 7.

| | Fiscal Year Ended | | | | |
|---|---|------------------------------|------------------------------|------------------------------|----------------------------|
| | (in thousands except per share data) | | | | |
| | January 3, 2003 | December 28, 2001 | December 29, 2000 | December 31, 1999 | January 1, 1999 |
| | Restated | Restated | Restated | Restated | Restated |
| Statement of Operations | | | | | |
| Sales | \$ 47,880 | \$ 50,237 | \$ 53,986 | \$ 58,955 | \$ 54,244 |
| Royalty and other income | 368 | 549 | 448 | 253 | 899 |
| Total revenues | 48,248 | 50,786 | 54,434 | 59,208 | 55,143 |
| Cost of sales | 24,099 | 28,203 | 26,329 | 22,935 | 18,533 |
| Gross profit | 24,149 | 22,583 | 28,105 | 36,273 | 36,610 |
| Selling, general and administrative expenses | | | | | |
| General and administrative | 8,959 | 8,746 | 8,593 | 7,939 | 6,770 |
| Marketing and selling | 16,833 | 20,043 | 21,254 | 19,879 | 18,709 |
| Research and development | 4,016 | 3,800 | 4,215 | 4,338 | 3,570 |
| Other charges | 1,454 | 7,780 | 15,276 | | |
| Total selling, general and administrative expenses | 31,262 | 40,369 | 49,338 | 32,156 | 29,049 |
| Operating income (loss) | (7,113) | (17,786) | (21,233) | 4,117 | 7,561 |
| Total other expense, net | (785) | (724) | (4,630) | (463) | (613) |
| Income before income taxes, minority interest and cumulative effect of change in accounting method | (7,898) | (18,510) | (25,863) | 3,654 | 6,948 |
| Income tax provision (benefit) | 8,805 | (3,649) | (6,758) | 945 | 2,056 |
| Minority interest | 75 | 139 | 87 | 419 | 662 |
| Net income (loss) before accounting change | (16,778) | (15,000) | (19,192) | 2,290 | 4,230 |
| Cumulative effect of accounting change | | | | | 1,680 |
| Net income (loss) | \$ (16,778) | \$ (15,000) | \$ (19,192) | \$ 2,290 | \$ 2,550 |
| Diluted income (loss) per share before effect of change in accounting method | \$ (0.98) | \$ (0.88) | \$ (1.25) | \$ 0.16 | \$ 0.30 |

Edgar Filing: STAAR SURGICAL COMPANY - Form 10-K/A

| | | | | | |
|---|-----------|-----------|-----------|---------|---------|
| Basic net income (loss) per share | \$ (0.98) | \$ (0.88) | \$ (1.25) | \$ 0.16 | \$ 0.19 |
| Diluted net income (loss) per share | \$ (0.98) | \$ (0.88) | \$ (1.25) | \$ 0.16 | \$ 0.18 |
| Weighted average number of basic shares | 17,142 | 17,003 | 15,378 | 14,157 | 13,542 |
| Weighted average number of diluted shares | 17,142 | 17,003 | 15,378 | 14,756 | 14,268 |

Balance Sheet Data

| | | | | | |
|---|-----------|-----------|-----------|-----------|-----------|
| Working capital | \$ 6,792 | \$ 16,780 | \$ 24,153 | \$ 28,037 | \$ 26,926 |
| Total assets | 45,220 | 64,650 | 79,745 | 85,008 | 73,290 |
| Notes payable and current portion of long-term debt | 5,845 | 8,216 | 7,944 | 2,691 | 2,312 |
| Long-term debt | | | | 13,673 | 10,021 |
| Stockholders' equity | \$ 30,551 | \$ 46,142 | \$ 58,060 | \$ 52,100 | \$ 47,356 |

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Except for the historical information contained in this Annual Report, the matters discussed in Management's Discussion and Analysis of Financial Condition and Results of Operations are forward-looking statements, the accuracy of which is necessarily subject to risks and uncertainties. Actual results may differ significantly from the discussion of such matters in the forward-looking statements. See Factors That May Affect Future Results of Operations.

Results of Operations

The following table sets forth the percentage of total revenues represented by certain items reflected in the Company's income statement for the period indicated and the percentage increase or decrease in such items over the prior period.

| | Percentage of Total Revenues | | | Percentage Change | |
|--------------------------------|--------------------------------|----------------------------------|----------------------------------|-------------------|------------------|
| | January 3, 2003 Restated | December 28, 2001 Restated | December 29, 2000 Restated | 2002 vs. 2001 | 2001 vs. 2000 |
| Total revenues | 100.0% | 100.0% | 100.0% | (5.0)% | (6.7)% |
| Cost of sales | 49.9% | 55.5% | 48.4% | (14.6)% | 7.1% |
| Gross profit | 50.1% | 44.5% | 51.6% | 6.9% | (19.6)% |
| Costs and expenses: | | | | | |
| General and administrative | 18.6% | 17.2% | 15.8% | 2.4% | 1.8% |
| Marketing and selling | 34.9% | 39.5% | 39.0% | (16.0)% | (5.7)% |
| Research and development | 8.3% | 7.5% | 7.7% | 5.7% | (9.8)% |
| Other charges | 3.0% | 15.3% | 28.1% | (81.3)% | (49.1)% |
| Total costs and expenses | 64.8% | 79.5% | 90.6% | (22.6)% | (18.2)% |
| Operating loss | (14.7)% | (35.0)% | (39.0)% | (60.0)% | (16.2)% |
| Other expense, net | (1.6)% | (1.4)% | (8.5)% | 8.4% | (84.4)% |
| Loss before income taxes | (16.3)% | (36.4)% | (47.5)% | 57.3% | (28.4)% |
| Income tax provision (benefit) | 18.2% | (7.2)% | (12.4)% | 341.5% | (46.0)% |
| Minority interest | 0.2% | 0.3% | 0.2% | (46.0)% | 59.8% |
| Net loss | (34.8)% | (29.5)% | (35.3)% | 11.9% | (21.8)% |

2002 Fiscal Year Compared to 2001 Fiscal Year

Revenues. Revenues for the year ended January 3, 2003 decreased over the year ended December 28, 2001 by 5.0% or \$2,538,000. The decrease in revenues was due primarily to a 14% decrease in IOL sales primarily in the United States. Approximately 66% of the decrease in IOL sales was the result of a decline in unit volume and 34% of the decrease was the result of a decline in average selling price (ASP). The decrease in IOL sales were partially offset by an 11% increase in sales in international markets of distributed products and a 33% increase in ICL sales. Unit volume of ICLs increased 34%, partially offset by a 1% decline in ASP. Sales of STAARVisc increased 205% on increased volume and Aquaflow sales increased 54% on increased volume and ASP. The Company expects sales of IOLs in the U.S. to increase in 2003 as a result of tighter management of the Company's independent sales force and the introduction of improved lens delivery systems.

Gross profit. Gross profit for the year ended January 3, 2003 was 50.1% of revenues compared to the year ended December 28, 2001 when it was 44.5% of revenues (including other charges of \$5.6 million related to inventory write-offs primarily as the result of voluntary product

Edgar Filing: STAAR SURGICAL COMPANY - Form 10-K/A

recalls). Excluding the other charges, gross profit for the year ended December 28, 2001 was 57.0%. The lower gross profit for the current year compared to the previous year (excluding other charges) is due to the high unit costs of IOL inventory manufactured last year during a period of low production volumes. Gross profit for the year was also impacted by a shift in product mix from IOLs with a higher gross profit margin to equipment and other distributed product with a lower gross profit

margin. Gross profit margin has improved sequentially each quarter since the second quarter of 2002. The Company expects gross profit to continue to improve as the high cost inventory is depleted and the Company's strategy to improve efficiency yields additional cost savings.

Marketing and selling expenses. Marketing and selling expenses for the year ended January 3, 2003 were 34.9% of revenues compared to 39.5% of revenues for the year ended December 28, 2001. In terms of dollars, marketing and selling expenses for 2002 decreased \$3.2 million or 16.0% over 2001 due to cost containment measures which have reduced overall spending in the U.S. and the approximate \$1.6 million in cost savings the Company has realized as a result of subsidiary closures in the previous year.

Other charges. Other charges for the year ended January 3, 2003 were approximately \$1.5 million compared to the year ended December 28, 2001 when other charges were \$7.8 million. The \$1.5 million in charges taken during 2002 related to the recognition of deferred losses resulting from the translation of foreign currency statements into U.S. dollars of subsidiaries that were closed and employee separation.

Other expense, net. Other expense, net for the year ended January 3, 2003 increased \$61,000 over the year ended December 28, 2001. This increase was due to increased interest income due to prior year notes receivable reserves and write-off of previous interest, offset by decreased income from the Company's joint venture with Canon-STAAR, and increased foreign exchange losses.

Income taxes. During the year ended January 3, 2003, the Company recorded a valuation allowance of \$9.0 million against its deferred tax assets. This non-cash charge reduced the deferred tax assets on the balance sheet to zero. The assets were created as a result of income tax benefits that were recorded on U.S. operating losses incurred during the restructuring and reorganization accomplished in 2000 and 2001. No deferred tax benefits were recorded on operating losses in 2002. Current accounting standards place significant weight on a history of recent cumulative losses in determining whether or not a valuation allowance is necessary. Forecasts of future taxable income are not considered sufficient positive evidence to outweigh a history of losses. Accordingly, the assets were reserved in full. The Company's federal net operating loss carryforwards are not impacted and can continue to be utilized for up to 20 years.

Legislation enacted on March 9, 2002 (HR 3090) enabled the Company to carryback a portion of the federal 2001 net operating loss to 1996, 1997 and 1998. Since this legislation was not enacted as of the end of fiscal year 2001, the benefit of \$959,000 from this carryback was recorded in 2002.

2001 Fiscal Year Compared to 2000 Fiscal Year

Revenues for the year ended December 28, 2001 were \$50.8 million, representing a 6.7% decrease over the \$54.4 million in revenues for the year ended December 29, 2000. The decrease in revenues resulted primarily due to decreased sales of the Company's Elastia and Elastimide silicone intraocular lenses due to the impact of a voluntary product recall in the second quarter of 2001. The decrease in silicone IOL sales was partially offset by increased sales of the Company's Collamer, Toric, and acrylic IOLs. The Company experienced a continued shift in product mix in fiscal 2002. Revenues also decreased in 2001 for sales in 2000 of subsidiaries that were closed in the same year and sales of the Company's SonicWAVE Phacoemulsification System also decreased. This decrease was due to the elimination of a dedicated sales force as a result of cost containment measures taken during fiscal 2001 and a general decline in the economy resulting in a decline in capital equipment spending. In addition to increased sales of Collamer, Toric and acrylic IOLs, sales of the Company's AquaFlow Device, which was approved for sale in the United States in the third quarter of fiscal 2001 and STAARVISC II also increased.

The Company is expanding its market focus beyond the cataract market to also include the refractive and glaucoma markets. The Company anticipates that its growth in the refractive and glaucoma product markets will

increase significantly as the Company's refractive lenses (ICL and Toric IOL) and its AquaFlow Device continue to gain market acceptance and regulatory approvals. The Company believes its sales of products used for the treatment of cataracts will grow with the introduction or reintroduction of various products including the Collamer three-piece IOL, STAARVISC II, UltraVac V1 tubing and the SonicWAVE Phacoemulsification System.

Cost of sales. Cost of sales were \$28.2 million or 55.5% of revenue for the year ended December 28, 2001 compared to \$26.3 million or 48.4% of revenue for the year ended December 29, 2000. The increase in cost of sales resulted from a 23% increase in inventory write-offs over the prior year, primarily relating to voluntary product recalls. Excluding the impact of inventory write-offs, cost of sales as a percent of revenues increased from 38.9% in fiscal 2000 to 43.0% in fiscal 2001. This increase was primarily due to increased unit costs of silicone IOLs and a change in product mix. Silicone IOL unit costs increased significantly due to lower production levels necessitated by reduced sales demand and improved inventory management.

General and administrative. General and administrative expense for the year ended December 28, 2001 was \$8.7 million, or 17.2% of revenue, as compared to \$8.6 million, or 15.8% of revenue for the year ended December 29, 2000. The primary reason for the increase as a percent of revenue was due to decreased revenues. The slight increase in dollars is primarily attributable to relocation costs of executive management, increased administrative salaries, and increased professional fees offset by decreased expenses from a subsidiary that was closed in the prior year.

Marketing and selling. Marketing and selling expense for the year ended December 28, 2001 was \$20.0 million or 39.5% of revenue, as compared to \$21.3 million or 39.0% of revenue for the year ended December 29, 2000. The primary reason for the increase as a percent of revenue was due to decreased revenues. Actual expense decreased by \$1.2 million due to decreased commissions, decreased costs from a subsidiary that was closed in fiscal 2000 and cost containment measures taken during fiscal 2001.

Research and development. Research and development expense for the year ended December 28, 2001 was \$3.8 million, or 7.5% of revenue as compared to \$4.2 million or 7.7% of revenue for the year ended December 29, 2000. Research and development expense decreased over the prior year due primarily to decreased staffing during the first six months of 2001.

Other charges. In June 2001 management completed an extensive operational review of the Company. Based upon that review, in August 2001 the Company implemented a plan that management believes will allow it to become profitable. As a result of implementing the plan, the Company significantly changed its manufacturing processes and locations, including consolidating lathing activity into the Swiss manufacturing site from the current dual site operations and reducing molded lens capacity at the California site. The Company also reduced its workforce and closed certain overseas operations. In conjunction with the implementation of the plan, the Company recorded pretax charges of approximately \$7.8 million in the third and fourth quarters of the 2001 fiscal year. Planned charges included approximately \$3.7 million in fixed asset write-offs, \$0.3 million in severance and employee relocation costs, and \$1.0 million for subsidiary closures. Additionally, the Company reserved \$2.1 million of notes receivable from former officers and directors of the Company and paid \$0.7 million for the early termination of a consulting contract with the president of one of the Company's European subsidiaries.

The Company also wrote off \$6.4 million of inventory related to voluntary product recalls and excess and obsolete inventory in the second and fourth quarters of 2001. The amount is included in cost of sales at December 28, 2001.

Other expense, net. Other expense, net for the year ended December 28, 2001 was approximately \$0.7 million or 1.4% of revenues as compared to approximately \$4.6 million or 8.5% of revenues for the year ended December 29, 2000. This decrease resulted from decreased interest expense, amounts written off in fiscal 2000 related to the Company's joint venture with Canon-STAAR Co., Inc., decreased interest income of \$0.9 million on recording notes receivable reserves and write-off of previous interest, and decreases in other income from legal

settlements over the prior year.

Income tax benefit. The income tax benefit was \$3.6 million for the year ended December 28, 2001 as compared to a benefit of \$6.8 million for the year ended December 29, 2000. The primary reason for this decrease relates to decreased U.S. losses over the prior fiscal year resulting in a lower overall tax benefit. The tax benefit for fiscal 2001 was further reduced by approximately \$2.8 million in valuation allowances that were recorded against the Company's deferred tax assets.

2000 Fiscal Year Compared to 1999 Fiscal Year

Revenues. Revenues for the year ended December 29, 2000 were \$54.4 million, representing an 8.1% decrease over the \$59.2 million in revenues for the year ended December 31, 1999. The primary reasons for the decrease in revenues were the reduced U.S. dollar amounts recorded by international subsidiaries due to the strength of the U.S. dollar as compared to foreign currencies, most specifically the German Mark, decreased sales to the Company's joint venture, Canon-STAAR Company, Inc., the continuing decline in sales of the Company's silicone IOLs in Europe and lower average selling prices on international sales of the Company's ICLs due to the change from direct selling to selling through international distributors. These decreases were offset by increased sales of the SonicWAVE Phacoemulsification System, which was introduced in the third quarter, increased revenue from the sales of the Collamer single piece IOL, approved for sale in April 2000, increased revenues from sales of the Toric IOL and increased revenues from a full year of sales of custom surgical packs to our U.S. customers, which began in mid-year 1999. Other revenue in 2000 increased over 1999 by \$195,000.

Cost of sales. Cost of sales increased to 48.4% of revenue for the year ended December 29, 2000 from 38.7% of revenue for the year ended December 31, 1999. The primary reasons for this 14.8% increase relates to an inventory write-off of \$5.2 million, recorded during the second quarter of 2000, of various items that no longer fit the Company's future direction. Additionally, despite higher average selling prices for IOLs, higher average unit cost caused the cost of sales as a percentage of revenue exclusive of the above-mentioned write-off to increase slightly to 38.8%. The increase in average selling price was due to the change in product mix to the Company's premium priced IOLs (Toric and Collamer). The higher average cost of IOLs was due principally to the changes in product mix to the Collamer IOL and, to a lesser extent; increased unit cost due to lower manufacturing activity levels which resulted in the units produced carrying a higher per unit cost from absorption of fixed expenses. Additionally, the full year of sales of custom surgical packs in the U.S. have a higher cost of sales as a percentage of sales when compared to the other products the Company offers.

General and administrative. General and administrative expense for the year ended December 29, 2000 was \$8.6 million, or 15.8% of revenue, as compared to \$7.9 million, or 13.4% of revenue for the year ended December 31, 1999. This increase in dollars was primarily attributable to increases in expenditures for professional service fees, expenses recorded in the second quarter at the time of the Company's restructuring plan, and increased expenses year over year from subsidiaries acquired or created in late 1999. The increase as a percent of revenues was due to the expenses increasing at a rate greater than the current growth rate of revenues.

Marketing and selling. Marketing and selling expense for the year ended December 29, 2000 was \$21.3 million or 39.0% of revenue, as compared to \$19.9 million or 33.6% of revenue for the year ended December 31, 1999. The primary reasons for this increase was the compensation and travel costs of direct sales management hired in late 1999 and 2000 to sell IOLs and the Company's SonicWAVE Phacoemulsification Systems, increased commissions generated by the graduated commission schedule which has higher percentage rates as IOL sales prices increase, and average selling price increases over 1999 due to the change in IOL mix to the Company's proprietary IOLs. Additionally, the Company has continued to increase the expenses for product management to prepare for broader entry into the refractive and glaucoma markets. These increases were offset, in part, as a result of the reduced U.S. dollar amounts recorded by international subsidiaries due to the strength of the U.S. dollar as compared to foreign currencies, most specifically, the German Mark.

Research and development. Research and development expense for the year ended December 29, 2000 was \$4.2 million, or 7.7% of revenue as compared to \$4.3 million or 7.3% of revenue for the year ended

December 31, 1999. Research and development expense decreased slightly over the prior year due to a reduction in research and development staffing offset by increased spending related to the monitoring of clinical trials for the ICL for the correction of myopia, the ICL for the correction of hyperopia, and the AquaFlow Device. Additionally, expenses relating to the development and improvement of the Company's SonicWAVE Phacoemulsification System increased.

Other charges. On June 22, 2000 the Company announced the details of its plan of restructuring. In conjunction with the implementation of the plan, the Company recorded a pre-tax charge to earnings of \$13.8 million in the second quarter of fiscal 2000. The charges include approximately \$0.9 million for restructuring of certain subsidiaries, approximately \$4.0 million to write-off patents that were considered questionable in providing future value to the Company, approximately \$1.9 million of costs incurred by the Company relating to activities that were abandoned, approximately \$4.1 million relating to severance and other employee separation costs, approximately \$1.9 million relating to the disposition of investment and assets related to the Company's abandoned entry into the Lasik market, and approximately \$1.0 million relating to the closure of a foreign subsidiary. 19 employees were laid-off, terminated or resigned as part of the Company's restructuring plan. Also included is a \$1.5 million charge related to a note receivable from a former officer, which is currently under-collateralized.

Other expense, net. Other expense, net for the year ended December 29, 2000 was approximately \$4.6 million or 8.5% of revenues as compared to approximately \$0.5 million or .8%% of revenues for the prior year. The primary reason for this increase was a \$4.7 million charge the Company recorded relating to the write-off of its Japanese joint venture.

Income tax provision. Income tax benefit was \$6.8 million for the year ended December 29, 2000 as compared to a provision of \$0.9 million for the year ended December 31, 1999. The reasons for the change relate to the dramatic reduction in income before income taxes, which was due primarily to the charges taken in the second quarter totaling \$24 million before income taxes. During 2000, the Company recorded a deferred tax asset that resulted from the losses recorded for the year. The Company would have been profitable in the 2000 fiscal year with the exclusion of charges relating to the restructuring plan and the reserve for notes receivable.

Liquidity and Capital Resources

The Company has funded its activities over the past several years principally from cash flow generated from operations, credit facilities provided by institutional domestic and foreign lenders, the private placement of Common Stock and the exercise of stock options and warrants.

Net cash provided by (used in) operating activities was \$0.6 million, (\$2.5) million, and (\$5.0) million for fiscal 2002, 2001, and 2000, respectively. For fiscal 2002, cash provided by operations was the result of the net loss, adjusted for depreciation, amortization, deferred income taxes, and other non-cash charges, and decreases in working capital primarily accounts receivable, inventory, and accounts payable. For fiscal 2001, cash used in operations was the net loss, adjusted for depreciation, amortization, deferred income taxes, and non-cash restructuring and inventory write-downs. For fiscal 2000, cash used in operations was the net loss, adjusted for depreciation, amortization, the write-down of the Company's investment in its Japanese joint venture, deferred income taxes, and non-cash restructuring and inventory write-downs partially offset by changes in working capital primarily accounts receivable, inventories and accounts payable.

Accounts receivable was \$6.0 million in 2002, \$7.5 million in 2001, and \$9.7 million in 2000 due to lower sales but also due to increased collection efforts. Days sales outstanding (DSO) improved from 64 days in 2000; to 54 days in 2001; to 45 days in 2002. The Company does not believe that the trend of lower DSO will continue in 2003 below the 45 days realized in 2002.

Edgar Filing: STAAR SURGICAL COMPANY - Form 10-K/A

Inventory in 2002, 2001, and 2000 was \$11.8 million, \$15.2 million, and \$20.8 million, respectively. Days inventory on hand decreased from 285 days in 2000; to 195 days in 2001; to 176 days in 2002. Decreases in

inventory in 2000 and 2001 totaling \$5.2 million and \$6.4 million, respectively, were the result of write-offs of excess and obsolete inventory and inventory related to voluntary product recalls. The decrease in inventory in 2001 was partially offset by higher cost inventory that was produced during the year as a result of decreased production volume. This high cost inventory was sold during 2002 and replaced with lower cost inventory resulting in an overall decrease in inventory of \$3.4 million over 2001. The Company expects that for 2003, the value of its inventory will remain approximately \$12.0 million and that the trend of decreasing inventory will not continue.

Accounts payable in 2002, 2001, and 2000 was \$4.6 million, \$5.6 million, and \$6.2 million, respectively. The decreases in 2000 and 2001 were the result of companywide cost savings measures implemented during those years. The benefits of those cost savings measures continued into 2002. However, the decrease at January 3, 2003 is principally due to plant shutdowns during the Christmas holidays which resulted in a change in the timing of payments.

Net cash used in investing activities was approximately \$406,000, \$705,000, and \$4.1 million for fiscal 2002, 2001, and 2000, respectively. The principal investments of the Company are in property and equipment. Investments in property and equipment were \$874,000, \$1.2 million, and \$3.3 million for fiscal 2002, 2001, and 2000, respectively. The investments are generally made to upgrade and improve existing production equipment and processes. In fiscal 2000, additional expenditures were made to set up or expand production facilities in the U.S. and in Switzerland for new products. The Company expects to spend approximately \$1.0 million on property and equipment in 2003.

Net cash (used in) provided by financing activities were approximately (\$592,000), (\$1.7 million), and \$12.2 million for fiscal 2002, 2001, and 2000, respectively. The Company had a \$7.0 million line of credit with a domestic lender which matured on March 29, 2002, and was amended and restated from time to time during the year ended January 3, 2003. The line of credit, as modified, extends the maturity date to March 31, 2003, included the release of restricted cash in the amount of \$2.0 million in order to pay down the note and provides for monthly decreases in availability through February 2003 totaling \$4.0 million. The Company's obligation to the lender is secured by a first priority lien on substantially all of the Company's assets and bears interest at a rate equal to the prime rate (4.25% at January 3, 2003) plus an applicable interest margin from 1% to 5% which is based on the Company's ratio of funded debt to earnings before interest, taxes, depreciation, and amortization (EBITDA) at each fiscal quarter on a trailing 12-month basis. In addition, the Company is required to pay a commitment fee .25% to 1.25% of the unused amount of the line of credit also based on a ratio of funded debt to EBITDA. Since the Company reported losses throughout 2002, it was charged the maximum total interest rate allowed under the agreement of prime plus a 5% margin (9.25%) and the maximum commitment fee of 1.25% at January 3, 2003.

The agreement also requires the Company to satisfy certain financial tests, which include positive and negative covenants such as the maintenance of certain levels of liquidity, operating cash flows, tangible net worth, and operating income. As of January 3, 2003, the Company was not in compliance with the tangible net worth covenants of the agreement due to the valuation allowance recorded against the Company's deferred tax assets. The Company has obtained a waiver from the lender who agreed to waive the events of default resulting from the covenant violations. Borrowings outstanding under the note as of January 3, 2003 and December 28, 2001, were approximately \$2.8 million and \$5.7 million, respectively. As of January 3, 2003 and December 28, 2001, the note provided for borrowings of up to \$3.7 million and \$7.0 million, respectively.

On March 26, 2003, the Company and its domestic lender executed an agreement to extend the maturity date of the Company's \$3.0 million line-of-credit for one year to March 31, 2004. The line-of-credit bears interest at a rate equal to the prime rate (4.25% at January 3, 2003) plus an interest margin of 5%. In addition, the Company is required to pay a commitment fee of 1.25% per annum of the unused amount of the line-of-credit. All other terms and conditions are generally unchanged except that the cash flow and operating income covenants of the agreement do not commence until the third quarter of 2003 and minimum tangible net worth covenants were reduced.

A subsidiary of the Company has a revolving credit facility with a Swiss bank, which as amended in fiscal 2001, provides for borrowings of up to 4.5 million Swiss Francs CHF (\$3.2 million based on the exchange rate on January 3, 2003). The credit facility is divided into two parts: Part A provides for borrowings of up to CHF 3.0 million (\$2.1 million based on the exchange rate on January 3, 2003) and does not have a termination date; Part B provides for borrowings of up to CHF 1.5 million (\$1.1 million based on the exchange rate on January 3, 2003). The loan amount under Part B of the agreement reduces by CHF 250,000 (\$178,000 based on the exchange rate on January 3, 2003) semi-annually beginning June 30, 2002. The credit facility is secured by a general assignment of claims.

The loan agreement provides for borrowings on a current or fixed-term basis. The interest rate on current advances is 6.5% per annum at January 3, 2003 plus a commission rate of 0.25%, payable each quarter. The base interest rate for fixed-term advances follows Euromarket conditions for loans of a corresponding term and currency plus an individual margin. The fixed-term rate at January 3, 2003 was 4.6%. Borrowings outstanding under the current account as of January 3, 2003 were CHF 90,000 (\$64,000 based on the exchange rate on January 3, 2003). Fixed term advances at January 3, 2003 were CHF 4.1 million (\$2.9 million based on the exchange rate on January 3, 2003).

A subsidiary of the Company has a revolving credit facility with a German bank that provides for borrowings of up to approximately 200,000 EUR (\$207,000 at the exchange rate on January 3, 2003) at an interest rate of 8.5%. The loan, originally due February 28, 2003, was extended on October 8, 2002 to August 31, 2003. Payments in the amount of 50,000 EUR (\$52,000 at the exchange rate on January 3, 2003) were due monthly beginning December 31, 2001. The amended agreement reduced the monthly payment to 25,000 EUR (\$26,000 at the exchange rate on January 3, 2003). The bank also agreed to waive the September 2002 and October 2002 payments. There were no other changes to the original terms of the agreement. The loan is secured by an assignment of the subsidiary's accounts receivable and inventory and is personally guaranteed by the subsidiary's president. There are no financial covenants included in the agreement and no borrowings outstanding as of January 3, 2003.

The subsidiary of the Company negotiated another credit facility with a different German bank to replace the one that expires on August 31, 2003. The new agreement, effective January 13, 2003, provides for borrowings of up to 210,000 EUR (\$199,000 at the exchange rate on the date of the agreement) at an interest rate of 8.5%. The note is due November 30, 2003 and is personally guaranteed by the subsidiary's president. The agreement includes a covenant which prevents the subsidiary from paying dividends.

The following table represents the Company's known contractual obligations at January 3, 2003.

| Contractual Obligations | Payments Due by Period | | | | |
|-----------------------------|------------------------|------------------|-----------------|--------------|-------------------|
| | Total | Less Than 1 Year | 1-3 Years | 3-5 Years | More Than 5 Years |
| | (In thousands) | | | | |
| Long-term debt Obligations | \$ | \$ | \$ | \$ | \$ |
| Capital Lease Obligations | | | | | |
| Operating Lease Obligations | 1,647 | 713 | 879 | 55 | |
| Purchase Obligations | 2,865 | 1,065 | 1,800 | | |
| Other long-term liabilities | 89 | | 89 | | |
| Total | \$ 4,601 | \$ 1,778 | \$ 2,768 | \$ 55 | \$ |

The Company depends on external sources (banks and capital markets) for the funding it needs to operate the business. Unexpected conditions have arisen and can continue to arise that could cause the Company to be in violation of its lender's financial covenants. The Company believes it

has sufficient cash available through its bank credit facilities and cash from operations to fund existing operations and that it could obtain alternate

financing, if necessary, although this is not certain. The decision of any one of the Company's lenders not to renew its line of credit could have a material adverse affect on the Company and the costs associated with obtaining alternate financing could be significant.

Critical Accounting Policies

The Company believes the following represent its critical accounting policies.

Revenue Recognition. In general, the Company supplies foldable IOLs on a consignment basis to customers, primarily ophthalmologists, surgical centers, hospitals and other eye care providers and recognizes sales when the IOLs are implanted. Sales of all other products, including sales to foreign distributors, are generally recognized upon shipment.

Revenue from license and technology agreements is recorded as income, when earned, according to the terms of the respective agreements.

Impairment of Long-Lived Assets. Intangible and other long lived-assets are reviewed for impairment whenever events such as product discontinuance, plant closures, product dispositions or other changes in circumstances indicate that the carrying amount may not be recoverable. In reviewing for impairment, the Company compares the carrying value of such assets to the estimated undiscounted future cash flows expected from the use of the assets and their eventual disposition. When the estimated undiscounted future cash flows are less than their carrying amount, an impairment loss is recognized equal to the difference between the assets' fair value and their carrying value.

Goodwill, which has an indefinite life and was previously amortized on a straight-line basis over the periods benefited, is no longer amortized to earnings, but instead is subject to periodic testing for impairment. Intangible assets determined to have definite lives are amortized over their remaining useful lives. Goodwill of a reporting unit is tested for impairment on an annual basis or between annual tests if an event occurs or circumstances change that would reduce the fair value of a reporting unit below its carrying amount. As provided under SFAS 142, the initial testing of goodwill for possible impairment was completed within the first six months of 2002 and no impairment has been identified. As of January 3, 2003, the carrying value of goodwill was \$6.4 million.

The Company also has other intangible assets consisting of patents and licenses, with a gross book value of \$14.0 million and accumulated amortization of \$5.0 million as of January 3, 2003. The Company capitalizes the costs of acquiring patents and licenses as well as the legal costs of successfully defending its rights to these patents. Amortization is computed on the straight-line basis over the estimated useful lives, which are based on legal and contractual provisions, and range from 10 to 20 years.

Deferred Taxes. The Company recognizes deferred tax assets and liabilities for temporary differences between the financial reporting basis and the tax basis of the Company's assets and liabilities along with net operating loss and credit carryforwards. A valuation allowance is recognized if, based on the weight of available evidence, it is more likely than not that some portion or all of the deferred tax asset may not be realized. The impact on deferred taxes of changes in tax rates and laws, if any, are applied to the years during which temporary differences are expected to be settled and reflected in the financial statements in the period of enactment.

In 2002, due to the Company's recent history of losses, an increase to the valuation allowance was recorded as a non-cash charge to tax expense in the amount of \$9.0 million. As a result, the valuation allowance fully offsets the value of deferred tax assets on the Company's balance sheet as of January 3, 2003. If in the future, the Company determines it will be able to utilize all or part of the deferred tax assets which have a valuation allowance of \$18.6 million at January 3, 2003, we would reverse the valuation allowance, which would result in an income tax benefit.

Factors That May Affect Future Results of Operations

Our short and long-term success is subject to many factors that are beyond our control. Stockholders and prospective stockholders in the Company should consider carefully the following risk factors, in addition to other information contained in this report. This Annual Report on Form 10-K contains forward-looking statements, which are subject to a variety of risks and uncertainties. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of various factors including those set forth below.

The Company may not be able to fund its future growth or react to competitive pressures if it lacks sufficient funds.

The Company depends on external sources (banks and capital markets) for the funding it needs to operate the business. Unexpected conditions have arisen and can continue to arise that could cause the Company to be in violation of its lender's financial covenants. The Company believes it has sufficient cash available through its bank credit facilities and cash from operations to fund existing operations and that it could obtain alternate financing, if necessary, although this is not certain. The decision of any one of the Company's lenders not to renew its line of credit could have a material adverse effect on the Company and the costs associated with obtaining alternate financing could be significant.

We have a history of losses.

We have reported losses in each of the last three fiscal years and have an accumulated deficit of \$40.8 million as of January 3, 2003. If losses from operations continue, they could adversely affect the market price for our common stock, and our ability to maintain existing financing and obtain new financing. Despite our restructuring efforts, there can be no assurance that we will receive the intended benefits from these changes or that we will be successful in restoring the profitability of the Company.

We risk losses through litigation.

We are party to various claims and legal proceedings arising out of the normal course of our business. These claims and legal proceedings relate to contractual rights and obligations, employment matters, stockholder suits, and claims of product liability. While there can be no assurance that an adverse determination of any such matters could not have a material adverse impact in any future period, we do not believe, based upon information known to us, that the final resolution of any of these matters will have a material adverse effect upon our consolidated financial position or results of operations and cash flows.

We have been in default of the terms of our domestic loans and have been required to reduce our principal balances, limiting our access to credit.

During recent periods, we have failed to comply with some of the covenants in our principal domestic loan, including covenants that we maintain minimum levels of operating income, cash flow and tangible net worth. Accordingly, we have had to seek waivers from our lender or modifications of our lending agreement. Among other things, we have agreed to monthly reductions of the balance of our principal domestic loan which reduces it from \$7.0 million to \$3.0 million when it is due on March 31, 2003. As of January 3, 2003, the principal balance of the loan was approximately \$2.8 million. If we fail to meet the covenants in our loans in the future, we may not be able to secure further waivers or amendments from our lenders, who may instead seek payment on their loans and, if we fail to pay, to foreclose on the collateral for their loans. We have pledged substantially all of our assets as security for our existing loans. Our collateral pledge may make it more difficult for us to

obtain additional financing on advantageous terms, if at all.

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 product 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. 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. 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.

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

We devote substantial resources to research and development. The research and development process is expensive, prolonged and entails considerable uncertainty. Development of new implantable technology, from discovery through testing and registration to initial product launch, typically takes between three and seven years. This period varies considerably from product to product and country to country. Because of the complexities and uncertainties associated with 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 such products successfully. These may take longer and cost more to develop and may be less successful than we currently anticipate. It is possible that few or none of the products in our development pipeline 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 impact 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 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, which could affect our profitability.

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. The failure of our products to be so covered could cause our profits to decline.

Economic conditions and price competition may cause sales of our products used in elective surgical procedures to decline and reduce our profitability.

Some of our products are used in purely elective procedures. For example, many patients with refractive errors that could be successfully treated with ICLs can also obtain satisfactory vision with eyeglasses or conventional contact lenses. Except in cases where ICLs offer the only acceptable outcome, it is likely that insurers, HMOs and government payors generally will not pay for ICL implantation and that the patient will bear the full cost of the procedure. Individuals may be less willing to incur the costs of these procedures in weak or uncertain economic conditions, which could lead to a decline in the number of these procedures.

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 at 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 such circumstances, the Company has previously made voluntary recalls of its products. Such voluntary recalls may take place again in the future. Mandatory recalls can also take place if regulators or courts require them, even if the Company believes its 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 also damage our reputation. The inconvenience caused by recalls and related interruptions in supply, and the damage to our reputation, could cause some providers to discontinue using our products. The costs of recalls have severely impacted our revenues in recent periods.

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

The research, development, testing, manufacturing and marketing of our products are subject to extensive governmental regulation. Government regulation includes inspection of and controls over testing, manufacturing, safety and environmental controls, efficacy, labeling, advertising, promotion, record keeping, the sale and distribution of pharmaceutical products and samples and electronic records and electronic signatures. We are also subject to government regulation with respect to the prices we charge and the rebates we offer to customers. 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. The FDA approval process is typically lengthy and expensive, and approval is never certain. 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, our market value and operating results may decline. Even if the FDA or another regulatory agency approves a product, the approval may limit the indicated uses for a product, may otherwise limit our ability to promote, sell and distribute a product or may require post-marketing studies. If we are unable to obtain regulatory approval of our products, we will not be able to market these products, which would result in a decrease in our sales. Currently, we are actively pursuing approval for a number of our products from regulatory authorities in a number of countries, including, among others, the United States, Egypt, Taiwan, China, and the United Arab Emirates. Continued growth in our sales and profits will depend, in part, on the timely and successful introduction and marketing of some or all of these products.

The clinical trials required to obtain regulatory approvals are complex and expensive and their outcomes are uncertain. We incur substantial expense for, and devote significant time to, clinical trials, yet cannot be certain that the trials will ever result in the commercial sale of a product. Positive results from pre-clinical studies and early clinical trials do not ensure positive results in later clinical trials that form the basis of an application for regulatory approval. We may suffer significant setbacks in clinical trials, even after earlier clinical trials show promising results. Any of our products may produce undesirable side effects that could cause us or regulatory authorities to interrupt, delay or halt clinical trials of a pharmaceutical or medical device candidate. We, the FDA or another regulatory authority may suspend or terminate clinical trials at any time if they or we believe the trial participants face unacceptable health risks.

Noncompliance with applicable United States regulatory requirements can lead to fines, injunctions, penalties, mandatory recalls or seizures, suspensions of production, denial or withdrawal of pre-marketing approvals, recommendations by the FDA against governmental contracts and criminal prosecution. The FDA also has authority to request repair, replacement or refund of the cost of any device we manufacture or distribute. Regulatory authorities outside of the United States may impose similar sanctions for noncompliance with applicable regulatory requirements.

We face strong competition.

Our competitors, including Bausch & Lomb, AMO, Alcon, Pharmacia & Upjohn, Inc. and CIBA Vision, 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. In recent periods, the Company has lost significant market share to some of its competitors.

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, reaching 49% for the year ended January 3, 2003. The results of operations and the financial position of our offshore operations are generally 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 2002, 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. 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. Fluctuations in the value of the United States dollar against other currencies have had in the past, and may have in the future, a material adverse effect on our operating margins and profitability.

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 product 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 all 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 impacted our profitability in the past in several markets, including Germany, Austria, South Africa, France, Sweden, Norway, Canada and Australia, and we may experience such impacts 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 assure you 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 obtain 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. The loss or interruption of any of these suppliers could cause our revenue and profitability to decline and harm our customer relations.

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

The validation of a second manufacturing site is expensive both in terms of time and money and, therefore, has not been done. If there were to be a natural disaster, fire, or other serious business interruption at 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 and profitability.

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 also earn revenue 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 within the next 1 to 15 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.

The Company depends on key employees.

The Company depends on the continued service of its senior management and other key employees. The loss of a key employee could hurt the business. The Company could be particularly hurt if key employees went to work for competitors. The Company's future success depends on its ability to identify, attract, train and motivate other highly skilled personnel. Failure to do so may adversely affect future results.

The Company's Certificate of Incorporation and Bylaws could delay or prevent an acquisition or sale of the Company.

The Company's 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. This gives the Board of Directors the ability to deter, discourage or make more difficult a change in control of the 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.

The Company's 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 the Company.

The Company is 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 the Company's common stock or preventing changes in its management.

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.

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

Our stock price could be subject to significant fluctuations in response to factors such as quarterly variations in operating results, operating results which 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.

Foreign Exchange

Management does not believe that the fluctuation in the value of the dollar in relation to the currencies of its suppliers or customers in the last three fiscal years has adversely affected the Company's ability to purchase or sell products at agreed upon prices. No assurance can be given, however, that adverse currency exchange rate fluctuations will not occur in the future, which would affect the Company's operating results.

Inflation

Management believes inflation has not had a significant impact on the Company's operations during the past three years.

New Accounting Pronouncements

In August 2001, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standards (SFAS) No. 143, Accounting for Asset Retirement Obligations. SFAS No. 143 requires the fair value of a liability for an asset retirement obligation to be recognized in the period in which it is incurred if a reasonable estimate of fair value can be made. The associated retirement costs are capitalized as part of the carrying amount of the long-lived asset. SFAS No. 143 is effective for fiscal years beginning after June 15, 2002. The Company's adoption of SFAS No. 143 did not have a material impact on its operations or financial position.

In May 2002, the FASB issued SFAS 145, Rescission of FASB Statements No. 4, 44, and 64, Amendment of FASB Statement No. 13, and Technical Corrections. SFAS No. 145 eliminates Statement 4 (and Statement 64, as it amends Statement 4), which requires gains and losses from extinguishments of debt to be aggregated and, if material, classified as an extraordinary item, and thus, also the exception to applying Opinion 30 is eliminated as well. This statement is effective for years beginning after May 2002 for the provisions related to the rescission of Statements 4 and 64, and for all transactions entered into beginning May 2002 for the provision related to the amendment of Statement 13. The Company's adoption of SFAS No. 145 did not have a material impact on its operations or financial position.

In June 2002, the FASB issued SFAS No. 146, Accounting for Costs Associated with Exit or Disposal Activities , which addresses accounting for restructuring and similar costs. SFAS No. 146 supersedes previous accounting guidance, principally Emerging Issues Task Force (EITF) Issue No. 94-3. The Company will adopt the provisions of SFAS No. 146 for restructuring activities initiated after December 31, 2002. SFAS No. 146 requires that the liability for costs associated with an exit or disposal activity be recognized when the liability is incurred. Under EITF No. 94-3, a liability for an exit cost was recognized at the date of a company's commitment to an exit plan. SFAS No. 146 also establishes that the liability should initially be measured and recorded at fair value. Accordingly, SFAS No. 146 may affect the timing of recognizing future restructuring costs as well as the amount recognized.

In November 2002, the FASB issued Interpretation No. 45, Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness to Others, an interpretation of FASB Statements No. 5, 57 and 107 and a rescission of FASB Interpretation No. 34. This interpretation elaborates on the disclosures to be made by a guarantor in its interim and annual financial statements about its obligations under guarantees issued. The interpretation also clarifies that a guarantor is required to recognize, at inception of a guarantee, a liability for the fair value of the obligation undertaken. The initial recognition and measurement provisions of the interpretation are applicable to guarantees issued or modified after December 31, 2002 and are not expected to have a material effect on the Company's operations or financial position. The disclosure requirements are effective for financial statements of interim and annual periods ending after December 31, 2002. Significant guarantees that have been entered into by the Company as of January 3, 2003 are disclosed in Note 9 to the consolidated financial statements.

Edgar Filing: STAAR SURGICAL COMPANY - Form 10-K/A

In December 2002, the FASB issued SFAS No. 148, Accounting for Stock-Based Compensation Transition and Disclosure , which amends SFAS No. 123, Accounting for Stock-Based Compensation .

SFAS No. 148 provides alternative methods of transition for a voluntary change to the fair value based method of accounting for stock-based employee compensation. In addition, SFAS No. 148 amends the disclosure requirements of SFAS No. 123 to require more prominent and more frequent disclosures in financial statements of the effects of stock-based compensation. The transition guidance provisions of SFAS No. 148 are effective for fiscal years ending after December 15, 2002. The interim disclosure provisions are effective for financial reports containing condensed financial statements for interim periods beginning after December 15, 2002. The adoption of SFAS No. 148 did not have a material impact on the Company's financial position or results of operations. The Company will provide the interim disclosures required by SFAS No. 148 beginning in the first quarter of 2003.

In January 2003, the FASB issued FASB Interpretation No. 46, Consolidation of Variable Interest Entities, an interpretation of Accounting Research Bulletins (ARB) No. 51, Consolidated Financial Statements (FIN 46). FIN 46 clarifies the application of ARB No. 51 to certain entities in which equity investors do not have the characteristics of a controlling financial interest or do not have sufficient equity at risk for the entity to finance its activities without additional subordinated financial support from other parties. The Company does not believe the adoption of FIN 46 will have a material impact on its financial position or results of operations.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

In the normal course of business, our operations are exposed to risks associated with fluctuations in interest rates and foreign currency exchange rates. The Company manages its risks based on management's judgment of the appropriate trade-off between risk, opportunity and costs. Management does not believe that market risks are material to the results of operations or cash flows of the Company, and, accordingly, does not generally enter into interest rate or foreign exchange rate hedge instruments.

Interest rate risk. Our \$5.8 million of debt is split between domestic borrowings of \$2.8 million and borrowings of our international subsidiaries of \$3.0 million. Our domestic borrowings are linked to the prime interest rate and, thus, our interest rate expense will fluctuate with rate changes in the U.S. The majority of our international borrowings bear an interest rate that is linked to Euro market conditions and, thus, our interest rate expense will fluctuate with changes in those conditions. If interest rates were to increase or decrease by 1% for the year, our annual interest rate expense would increase or decrease by approximately \$60,000.

Foreign currency risk. Our international subsidiaries operate in and are net recipients of currencies other than the U.S. dollar and, as such, we benefit from a weaker dollar and are adversely affected by a stronger dollar relative to major currencies worldwide (Euro and Australian dollar). Accordingly, changes in exchange rates, and particularly the strengthening of the US dollar, may negatively affect our consolidated sales and gross profit as expressed in U.S. dollars. Additionally, approximately 51% of our debt is denominated in Swiss Francs and as such, we are subject to fluctuations of the Swiss Franc as compared to the U.S. dollar in converting the value of the debt in U.S. dollars. The U.S. dollar value of the debt is increased by a weaker dollar and decreased by a stronger dollar relative to the Swiss Franc.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.

Financial Statements and the Report of Independent Certified Public Accountants are filed with this Annual Report on Form 10-K in a separate section following Part IV, as shown on the index under Item 14(a) of this Annual Report.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE.

Not applicable.

PART III

ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT

IDENTIFICATION OF THE BOARD OF DIRECTORS

Our Certificate of Incorporation and our Bylaws divide our Board of Directors into three classes, designated Class I, Class II and Class III, with the number of directors in each class to be as nearly equal as possible, and with each class to be elected for a three-year term on a staggered basis. Our Bylaws permit the Board of Directors to fix the number of its members so long as there are no less than three directors and no more than seven directors. At present, the Board of Directors consists of five members. One member serves as a Class I director, two members serve as Class II directors, and two members serve as Class III directors. Mr. David Bailey presently serves as our Class I director, and is subject to re-election at the annual meeting of stockholders to be held in the year 2005. Mr. Donald Duffy and Dr. Volker D. Anhaeusser presently serve as our Class II directors, and will be subject to re-election at the annual meeting of stockholders to be held in the year 2003. Messrs. John R. Gilbert and David Morrison serve as our Class III directors, and are subject to re-election at the annual meeting of stockholders to be held in the year 2004. Information regarding the business experience of each nominee and director is provided below. There are no family relationships among our executive officers and directors.

David Bailey, Class I Director

Director since December 2000

Chairman of the Board of Directors since January 11, 2001

President and Chief Executive Officer

Age 46.

Prior to joining us in 2000, Mr. Bailey served as Global President of CIBA Vision Corporation's surgical business unit based in Atlanta, Georgia. As a member of that company's senior executive committee, Mr. Bailey was involved in the management of a business with revenue in excess of \$1 billion and employing over six thousand people. From April 1995 through May 1999, Mr. Bailey served on the global management boards of both Bausch & Lomb and ChironVision. In 1993, Mr. Bailey was the European Managing Director of Johnson & Johnson's European professional sector, with operating responsibility for the ophthalmic business of Johnson & Johnson's Iolab Corporation subsidiary, including both medical devices and pharmaceuticals. Mr. Bailey completed his formal education in the United Kingdom, obtaining a Master's degree from Durham University, and a Bachelor of Arts degree with honors from York University.

Mr. Donald Duffy, Class II Director

Director since February 2003

Chairman of Audit Committee

Age 66

Edgar Filing: STAAR SURGICAL COMPANY - Form 10-K/A

Mr. Duffy's relevant previous experiences include the position of Chief Financial Officer of Iolab Corporation subsidiary of Johnson & Johnson from 1987 to 1992, J & J Ultrasound Division of Johnson & Johnson from 1986 to 1987 and Alpha Wire Corporation from 1984 to 1985. Prior to his positions as Chief Financial Officer, he was the Chief Information Services Officer for J & J Products Division of Johnson & Johnson from 1976 to 1984 and held various financial positions for Johnson & Johnson from 1962 to 1976. Mr. Duffy earned an MBA in management from Pace University in 1972 and a BS in Accounting from the University of South Dakota in 1958. Mr. Duffy was appointed on January 29, 2003 to fill the vacancy created by the resignation of Dr. Peter Utrata. Mr. Duffy serves as chairman of the Company's audit committee.

Dr. Volker D. Anhaeusser, Class II Director

Director since April 2000

Age 47

Dr. Anhaeusser is a resident of Karlsruhe, Germany. He is a principal member and shareholder of the German law firm of Anhaeusser, Unger, & Bergien, whose specialty is corporate and business law. Dr. Anhaeusser received his Masters in Law degree in 1979 from Mainz University. Dr. Anhaeusser serves on the Board of Directors of several German based corporations, as well as serving on the Board of Directors of our subsidiary, Canon-STAAR Company, Inc.

John R. Gilbert, Class III Director

Director since February 2001

Age 66

Mr. Gilbert's senior executive experience includes a 12 year career with Iolab Corporation, a Johnson & Johnson company, and 18 years with Johnson & Johnson's operating company, Ethicon, Inc. At Iolab, Mr. Gilbert was promoted from Vice President, Marketing to President and, in 1987, to Vice Chairman. While at Iolab Mr. Gilbert was responsible for that company's franchise worldwide, while also serving as Vice President of Johnson & Johnson International. At Ethicon, Mr. Gilbert began as a sales representative and held a series of increasingly responsible positions, becoming Vice President, Sales and a member of the Management Board in 1976. He has had significant sales and general management experience in the areas of intraocular lenses, viscoelastic materials and other ophthalmic products. Mr. Gilbert is presently a Director of Rita Medical, a developer and marketer of a proprietary radio-frequency system for the treatment of cancerous and benign tumors. Mr. Gilbert is a veteran of the U.S. Army and a graduate of Texas A&M University with a Bachelor of Science degree in Industrial Technology.

David Morrison, Class III Director

Director since May 2001

Age 58

Mr. Morrison has 35 years experience in various executive positions, both within the United States and internationally. Since 1998, Mr. Morrison has been providing consulting services relating to marketing, with an emphasis in the field of surgical ophthalmology. Following the acquisition by Chiron Vision of Iolab Corporation in March 1995, Mr. Morrison was appointed President and Chief Operating Officer of the combined businesses, which were based in Claremont, California. Mr. Morrison began his career with Chiron Vision as President of International Operations in October 1994. Prior to joining Chiron Vision, Mr. Morrison was employed by the Gillette Company as Area Vice President for Europe. In 1981, Mr. Morrison joined Cooper Vision as its Area Vice President for Europe, Africa and the Middle East. When Mr. Morrison decided to end his career with Cooper Vision in 1989, he was President of International Operations and Co-Chief Operating Officer. Mr. Morrison began his career at Warner Lambert/Parke Davis in 1970, eventually attaining a senior marketing position. Mr. Morrison holds an Honors Degree in Economics and is a post-graduate in Business Administration.

IDENTIFICATION OF EXECUTIVE OFFICERS

David Bailey, President and Chief Executive Officer

See discussion of business experience above.

John Bily, Chief Financial Officer

Age 55

Mr. Bily joined the Company in January 2002. Before joining the Company, Mr. Bily spent 11 years with Allergan, Inc., an international pharmaceutical company, most recently as Vice President and Controller, Worldwide Operations, where he was responsible for the financial management of Allergan, Inc.'s global manufacturing and operations organization. Mr. Bily joined Allergan, Inc. in 1989 as Vice President and

Controller of Allergan Optical, the global contact lens and contact lens care division. Mr. Bily earned his Masters in Business Administration in Finance/Accounting from Arizona State University and his Bachelor of Arts degree in History from the University of Dallas. Mr. Bily also served in the United States Air Force.

John Santos, Senior Vice President, Planning and Corporate Development

Age 47

Mr. Santos has served as our Senior Vice President, Planning and Corporate Development since January 2001. Mr. Santos served as our Chief Financial Officer from May 2000 until December 2001, as Vice President-Controller from April 1999 and Controller from October 1992. Prior to 1992, Mr. Santos was Corporate Controller of Calmar, Inc. (now Calmar-St. Gobain), a manufacturer of trigger and fine mist sprayers, spray dispensers and pharmaceutical spray devices. He held various management positions at Calmar, Inc. from 1984 to 1992. Mr. Santos received a Masters of Business Administration from Pepperdine University and a Bachelor of Arts degree in Business Administration with an emphasis in Accounting from California State University, Fullerton.

Helene Lamielle, Vice President, Scientific Affairs

Age 45

Dr. Lamielle, who joined us in January 2002, is an experienced medical and surgical ophthalmologist with 11 years of ophthalmic industry experience in pharmaceuticals and medical devices and across major subspecialties such as retina, cataract and refractive surgery. Before joining us, Dr. Lamielle was Vice President of Scientific Affairs, Implantable Products at Bausch & Lomb Surgical, the ophthalmic surgery product unit of the global eye care firm. Her responsibilities included management of research and development for surgical products for cataract and refractive indications and management of Clinical and Regulatory Affairs for all surgical products. Dr. Lamielle earned her medical degree from the University of Lyon, France.

Nicholas Curtis, Senior Vice President, Sales and Marketing

Age 47

Mr. Curtis, who joined us in August 2002, is an experienced sales and marketing professional with over 20 years experience in selling and marketing cataract and refractive surgical products. Prior to joining the Company, Mr. Curtis served as Vice President for TLC Vision Inc. from 1998 to 2002, where he was responsible for managing the company's business development in the Great Lakes Region. Prior to 1998, Mr. Curtis held various sales management positions with Chiron Vision, Allergan Medical Optics, and American Medical Optics, a division of American Hospital Supply Corp. Mr. Curtis received a Bachelor of Science degree in Speech-Communication Studies from Northwestern University.

Guenther Roepstorff, President, Domilens GmbH

Age 58

Edgar Filing: STAAR SURGICAL COMPANY - Form 10-K/A

Mr. Roepstorff is the President and founder of Domilens GmbH, our German subsidiary, a position he has held since 1987. From 1983 to 1987, Mr. Roepstorff was managing director of Intermedics, where he was responsible for ophthalmic and cardiovascular products for the domestic German and the European markets. From 1979 to 1983, he established the Iolab Corporation intraocular lens business in Germany, Austria and Switzerland as an independent company within the Johnson & Johnson group of companies. For more than 10 years he held various management positions at Johnson & Johnson within the general surgery and dental product divisions.

COMPLIANCE WITH SECTION 16(a) OF THE SECURITIES ACT

Section 16(a) of the Securities Act requires our directors, executive officers and persons who own more than 10% of our Common Stock to file reports of ownership and changes in ownership of our Common Stock with the Securities and Exchange Commission. Directors, executive officers and persons who own more than 10% of our Common Stock are required by Securities and Exchange Commission regulations to furnish to us copies of all Section 16(a) forms they file.

To our knowledge, based solely upon our review of the copies of such reports or written representations from the reporting persons, we believe that during our 2002 fiscal year our directors, executive officers and persons who own more than 10% of our Common Stock complied with all Section 16(a) filing requirements with the exception of David Bailey, John Gilbert, David Morrison, John Bily, Helene Lamielle and Nicholas Curtis.

ITEM 11. EXECUTIVE COMPENSATION

SUMMARY COMPENSATION

The following table shows the compensation awarded, earned or paid over the past three fiscal years with respect to: (i) the Company's Chief Executive Officer during the 2002 fiscal year and (ii) the four other most highly compensated executive officers (in terms of salary and bonus) serving at the end of the 2002 fiscal year whose annual salary and bonus exceeded \$100,000 (the "named executive officers"):

| Name and Principal Position | Year | Annual Compensation | | Long-Term Compensation | | | | | |
|--|------|---------------------|---------------|--|---------------------------------------|--------------------------|---------|-------------------------|--------------------------------------|
| | | Salary (\$) | Bonus (\$) | Other Annual Compensation (\$)(1) | Awards | | Payouts | | |
| | | | | | Restricted Stock Awards (\$) | Securities Underlying | | LTIP Payouts (\$) | All Other Compensation (\$)(3) |
| | | | | | | Options/ SARs (2) | | | |
| David Bailey | 2002 | \$ 359,450 | | \$ 8,000 | | 210,000 | | \$ 29,039 | |
| Chairman, CEO and President | 2001 | \$ 300,000 | \$ 110,000 | \$ 8,000 | | 150,000 | | \$ 164,446 | |
| | 2000 | | | | | 500,000 | | | |
| John Bily | 2002 | \$ 192,308 | | | | 100,000 | | \$ 16,534 | |
| Chief Financial Officer | 2001 | | | | | | | | |
| | 2000 | | | | | | | | |
| John Santos | 2002 | \$ 159,471 | | | | | | \$ 7,572 | |
| Senior Vice President, Planning and Corporate Development | 2001 | \$ 155,000 | | | | | | \$ 10,937 | |
| | 2000 | \$ 142,308 | \$ 20,000 | \$ 10,984 | | 60,000 | | \$ 10,691 | |
| Helene Lamielle | 2002 | \$ 180,000 | | | | 75,000 | | \$ 6,325 | |
| Vice President, Scientific Affairs | 2001 | | | | | | | | |
| | 2000 | | | | | | | | |
| Nicholas Curtis | 2002 | \$ 61,538 | | | | 75,000 | | \$ 2,390 | |

Edgar Filing: STAAR SURGICAL COMPANY - Form 10-K/A

| | | | | | | |
|----------------------------|------|------------|-----------|------------|--------|-----------|
| Senior Vice President, | 2001 | | | | | |
| Sales and Marketing | 2000 | | | | | |
| Guenther Roepstorff | 2002 | \$ 216,898 | \$ 87,000 | \$ 14,362 | | |
| President, Domilens | 2001 | \$ 256,910 | \$ 43,389 | \$ 859,534 | | \$ 33,564 |
| GmbH | 2000 | \$ 249,669 | \$ 25,471 | \$ 22,131 | 50,000 | \$ 32,618 |

- (1) Included in this column are the costs of an automobile allowance for Mr. Bailey and Mr. Roepstorff and for Mr. Santos, taxes paid by the Company related to a bonus received in 2000. Also included for Mr. Roepstorff in 2001 are \$180,000 in consulting fees and \$658,000 for the early termination of the consulting arrangement, paid at a discount.
- (2) No stock appreciation rights were granted in 2002, 2001 or 2000. The options issued to Mr. Roepstorff in 2000 were cancelled in 2002 in connection with a purchase agreement between Mr. Roepstorff and the Company to acquire his remaining interest in our majority owned German subsidiary, Domilens GmbH. This transaction is further described in Certain Relationships and Related Transactions Purchase Agreement.
- (3) The amounts reported in this column, for all officers other than Mr. Bailey and Mr. Roepstorff, consist solely of the cost of life insurance premiums. Mr. Bailey's All Other Compensation includes the cost of life and disability insurance premiums, in addition to relocation related expenses of \$135,771 paid in 2001. Mr. Roepstorff's All Other Compensation includes the cost of pension plan contributions.

OPTION/SAR GRANTS IN LAST FISCAL YEAR

The following table provides certain information with respect to individual grants of stock options and/or stock appreciation rights in the 2002 fiscal year to each of the named executive officers:

| Name | Number of Securities Underlying Options/SARs Granted(2) (#) | % of Total Options/SARs Granted to Employees in Fiscal Year(3)(4) | Exercise or Base Price(2) (\$/Sh) | Expiration Date | Potential Realizable Value at Assumed Annual Rates of Stock Price Appreciation for Option Term(1) | |
|---------------------|--|---|--------------------------------------|-----------------|---|---------|
| | | | | | 5%(\$) | 10%(\$) |
| David Bailey | 150,000 | 21% | 3.81 | 1/2/2012 | 359,413 | 910,824 |
| | 60,000 | 8% | 5.19 | 5/29/2007 | 86,034 | 190,113 |
| John Bily | 100,000 | 14% | 3.29 | 12/11/2006 | 90,897 | 200,858 |
| John Santos | | | | | | |
| Helene Lamielle | 75,000 | 10% | 4.62 | 1/14/2007 | 95,732 | 211,542 |
| Nicholas Curtis | 75,000 | 10% | 3.45 | 7/14/2007 | 71,488 | 157,969 |
| Guenther Roepstorff | | | | | | |

- (1) The potential realizable dollar value of any given option is the difference between (i) the fair market value of the stock underlying such option as of the date of grant, adjusted to reflect hypothetical 5% and 10% annual growth rates simple interest from the date of grant of such option until the expiration date of such option, and (ii) the exercise price for such option. The 5% and 10% are hypothetical growth rates prescribed by the SEC for illustration purposes only and are not a forecast or prediction as to future stock prices. The actual amount that a named executive officer may realize will depend on various factors on the date the option is exercised, so there is no assurance that the value realized by a named executive officer will be at or near the value set forth above in the chart.
- (2) All options were granted at fair market value on the date of grant.
- (3) No SARs were granted to the named executive officers in the 2002 fiscal year.
- (4) The numerator in calculating this percentage includes options granted to each named executive officer in his capacity both as an officer (employee) and, if applicable, as a director. The denominator in calculating this percentage is 724,155, which represents options granted to all of the employees of the Company, including the named executive officers, which includes, if applicable, grants of options attributable to them in their capacities as directors.

**AGGREGATED OPTIONS/SAR EXERCISES IN LAST FISCAL YEAR AND
FISCAL YEAR-END OPTION/SAR VALUES**

The following table provides certain information with respect to the named executive officers concerning: (i) options exercised in fiscal year 2002; and (ii) the number and value of unexercised options as of the 2002 fiscal year end:

| <u>Name</u> | <u>Shares Acquired On Exercise(1) (#)</u> | <u>Value Realized(2) (\$)</u> | Number of Securities Underlying Unexercised Options/SARs At FY-End (#) | Value of Unexercised In-The-Money Options/SARs at FY-End(3) (\$) Exercisable/ Unexercisable |
|---------------------|--|--|--|---|
| | | | <u>Exercisable/Unexercisable</u> | <u>Unexercisable</u> |
| David Bailey | | | 820,000/40,000 | 186,000/0 |
| John Bily | | | 33,333/66,667 | 21,666/43,334 |
| John Santos | | | 82,999/20,001 | 0/0 |
| Helene Lamielle | | | 25,000/50,000 | 16,250/32,500 |
| Nicholas Curtis | | | 0/75,000 | 0/48,750 |
| Guenther Roepstorff | | | 0/0 | 0/0 |

- (1) No SARs were granted or exercised by any named executive officer in 2002, nor did any named executive officer hold any unexercised SARs at the end of the 2002 fiscal year. No options were exercised by any named executive officer in 2002.
- (2) The dollar values are calculated by determining the difference between the fair market value of the securities underlying the options and the price of the options at exercise.
- (3) The dollar value provided represents the cumulative difference in the fair market value of the Common Stock underlying all in-the-money options as of the last day of the 2002 fiscal year and the exercise prices for such options. Options are in-the-money if the fair market value of the underlying Common Stock as of the last day of the 2002 fiscal year exceeds the exercise price of such options. The fair market value of the Common Stock for purposes of this calculation is \$4.20, based upon the closing price for the Company's stock as quoted on the Nasdaq National Market on January 3, 2003, the last day of the Company's 2002 fiscal year.

COMPENSATION OF DIRECTORS

No cash fees were paid to directors for their service on the Board of Directors during the year 2002. Directors standing for election or re-election are granted options to purchase 60,000 shares of our Common Stock upon their election. Directors are elected for three-year terms. The option exercise price is the closing price of the Common Stock on the date of grant.

Upon reelection to the Board of Directors on May 30, 2002, Mr. Bailey received options to purchase 60,000 shares of our Common Stock at an exercise price of \$5.19. These options vest in three equal amounts of 20,000 shares during each year of service with the first vesting on the date of grant. On January 2, 2002, Dr. Anhausser received options to purchase 45,000 shares of our Common Stock at a price of \$3.81 for service as

Edgar Filing: STAAR SURGICAL COMPANY - Form 10-K/A

a director of Canon-STAAR Company Inc., a 50% joint venture of the Company with Canon Inc. and Canon Sales Co. Inc.

The Board of Directors can change the compensation of directors at any time.

EMPLOYMENT AGREEMENTS WITH NAMED EXECUTIVE OFFICERS

David Bailey, President, Chief Executive Officer and Chairman of the Board of Directors

On December 19, 2000, we entered into an employment agreement with Mr. David Bailey to act as our Chief Executive Officer and President. The agreement is for a term of three years and will be automatically renewed for successive three-year periods unless terminated pursuant to provisions stated in the agreement. In order to encourage Mr. Bailey to join the Company, he was granted an option to purchase 500,000 shares of our Common Stock at an exercise price of \$11.25 per share, the fair market value on the date of the agreement. The right to exercise the options vested in three installments over a period of two years beginning with the effective date of the agreement. In addition, we paid a bonus of \$110,000 in fiscal year 2001 representing the bonus forfeited by Mr. Bailey due to the termination of his prior employment and relocation costs.

The agreement provides for a base salary of \$300,000 in the first year, increasing to \$350,000 during the remaining of the term of the agreement. The agreement also provides for adjustments to Mr. Bailey's annual salary based on increases in the cost of living during the previous twelve months. Additionally, Mr. Bailey is entitled to an automobile allowance.

Each year during the term of the employment agreement, Mr. Bailey and the Compensation Committee will establish performance goals, including earnings, cash flow and other objectives, and so long as he meets those goals, Mr. Bailey is to receive an annual bonus of up to 60% of his base annual salary.

Under the terms of the agreement, Mr. Bailey's employment may be terminated for cause, upon Mr. Bailey's death or disability, or upon 12 months written notice by Mr. Bailey. If Mr. Bailey's employment is terminated by election of the Company or due to a change of control, Mr. Bailey will be entitled to receive severance equal to three years annual base salary, plus accrued bonus and vacation, and immediate vesting of any unvested options.

John Bily, Chief Financial Officer

On January 3, 2002, we entered into an employment agreement with Mr. John Bily to act as our Chief Financial Officer. The agreement does not have a stated term. In order to encourage Mr. Bily to join the Company, he was granted an option to purchase 100,000 shares of our Common Stock at an exercise price of \$3.29 per share, the fair market value on the date of the agreement. The right to exercise these options vests over a period of three years, and 33,333 shares are currently vested.

The agreement provides for a base salary, currently \$200,000, which may be adjusted periodically by the Company. Mr. Bily may also earn an annual bonus of no more than 40% of his annual salary upon achieving established performance goals.

Under the terms of the agreement, Mr. Bily's employment may be terminated for cause or poor performance, upon Mr. Bily's death, or upon 90 days written notice by Mr. Bily. If Mr. Bily's employment is terminated by the Company without cause, upon 90 days written notice, he will be entitled to severance equal to six months salary. Should Mr. Bily's employment be terminated due to a change of control, Mr. Bily will receive severance equal to one year's salary and the immediate vesting of any unvested stock options.

John Santos, Senior Vice President, Planning and Corporate Development

On April 28, 1999, we entered into an employment agreement with Mr. John Santos. The agreement is for a term of three years, and is automatically renewed upon the expiration of each term unless otherwise re-negotiated or terminated pursuant to its terms. Mr. Santos has worked in various capacities for us and in August 2001, was appointed as Senior Vice President, Planning and Corporate Development, with no other changes in his employment arrangement.

Pursuant to his employment agreement, Mr. Santos receives an annual salary of \$159,650 per year. This compensation may be increased at the discretion of the Board of Directors.

In conjunction with his agreement to continue providing services to us, Mr. Santos received an option to purchase 25,000 shares of our Common Stock at an exercise price of \$10.63 per share. The option vested in equal increments over a period of three years and became fully vested on June 16, 2002.

If Mr. Santos' employment is terminated as a result of a change of control, he will receive, in addition to any compensation earned through the effective date of his termination, one year's annual salary, the immediate vesting of any unvested option, and the principal amount and all accrued interest of any loan made to him by the Company will be forgiven.

Helene Lamielle, Vice President, Scientific Affairs

On January 22, 2002, we entered into an employment agreement with Dr. Helene Lamielle to act as our Vice President, Scientific Affairs. The agreement does not have a stated term. In order to encourage Dr. Lamielle to join the Company, she was granted an education reimbursement allowance of up to \$27,000 for an advanced degree. She was also granted an option to purchase 75,000 shares of our Common Stock at an exercise price of \$4.62 per share, the fair market value on the date of the agreement. The right to exercise these options vests over a period of three years, and 25,000 shares are currently vested.

The agreement provides for a base salary, currently \$200,000, which may be adjusted periodically by the Company. Dr. Lamielle may also earn an annual bonus of no more than 25% of her annual salary upon achieving established performance goals.

Under the terms of the agreement, Dr. Lamielle's employment may be terminated for cause or poor performance, upon Dr. Lamielle's death, or upon 90 days written notice by Dr. Lamielle. If Dr. Lamielle's employment is terminated by the Company without cause, she will be entitled to severance equal to six months salary. Should Dr. Lamielle's employment be terminated due to a change of control, she will receive severance equal to one year's salary and the immediate vesting of any unvested stock options.

Nicholas Curtis, Senior Vice President, Sales & Marketing

On July 12, 2002, we entered into an employment agreement with Mr. Nicholas Curtis to act our Sr. Vice President, Sales & Marketing for the U.S. and Canada. The agreement does not have a stated term. In order to encourage Mr. Curtis to join the Company, he was granted an option to purchase 75,000 shares of our Common Stock at an exercise price of \$3.45 per share, the fair market value on the date of the agreement. The right to exercise these options vests over a period of three years, none of which are currently vested. In addition, we have agreed to pay certain relocation costs associated with Mr. Curtis' upcoming relocation from his home in Illinois.

The agreement provides for a base salary, currently \$200,000, which may be adjusted periodically. Mr. Curtis may also earn an annual bonus of up to 50% of his annual salary upon achieving established performance goals. Should certain performance targets be exceeded, this amount could be increased.

Edgar Filing: STAAR SURGICAL COMPANY - Form 10-K/A

In February 2003, Mr. Curtis' employment agreement was amended to include a provision for termination due to a change of control. Should Mr. Curtis' employment be terminated due to a change of control, he will receive severance equal to one year's salary plus any accrued bonuses as calculated based upon length of employment and immediate vesting of any unvested stock options.

Guenther Roepstorff, President, Domilens GmbH

On January 3, 2003, our employment agreement with Mr. Guenther Roepstorff to act as President of our subsidiary, Domilens GmbH, was modified in connection with the purchase of his minority interest in Domilens.

The agreement, which expires December 31, 2007, provides for an annual salary of DM 450,000 (U.S. \$230,085 at January 3, 2003). In addition to his salary, Mr. Roepstorff is entitled to a 5% bonus on net income.

COMPENSATION COMMITTEE INTERLOCKS AND INSIDER PARTICIPATION

During fiscal year 2002, Dr. Volker Anhaeusser, Mr. John Gilbert and Mr. David Morrison served on our Compensation Committee. None of these individuals is employed by the Company. Except for Mr. Morrison, none of these individuals was a party to any transactions with the Company during fiscal year 2002. Mr. Morrison is the sole owner of DRM Strategic Services Ltd., which received consulting fees of \$73,000 during fiscal year 2002 under a Consulting Agreement with the Company. See Certain Relationships and Related Transactions Consulting Agreement.

Compensation issues were also brought before the full Board, which included Mr. David Bailey and Dr. Peter Utrata.

REPORT OF THE COMPENSATION COMMITTEE

The Report of the Compensation Committee of the Board of Directors shall not be deemed incorporated by reference by any general statement incorporating by reference this Annual Report on Form 10-K into any filing under the Securities Act of 1933 or under the Securities Exchange Act of 1934, except to the extent that the Company specifically incorporates this information by reference, and shall not otherwise be deemed filed under such Acts.

General. During the year 2002, the Compensation Committee was comprised of Mr. David Morrison, Mr. John Gilbert and Dr. Volker Anhaeusser. The Compensation Committee establishes specific awards under our equity plans, such as stock options, and determines the compensation for the Company's executive officers. Executive compensation can include salary, bonus, and option grants as well as other perquisites that vary with the level of responsibility.

In determining the compensation for a particular executive officer, the Compensation Committee was guided in the year 2002 by the following objectives:

attracting and retaining officers by maintaining competitive compensation packages; and

motivating officers to achieve and maintain superior performance levels.

The Compensation Committee believes that total compensation for executive officers should be sufficiently competitive with compensation paid by companies of similar size and market place position.

Base Compensation. Base pay is baseline cash compensation and is determined by market forces. The Compensation Committee sets base pay based on what it believes is comparable to compensation paid by companies of similar size and market place position.

Annual Cash Bonuses. The Compensation Committee, in its sole discretion, approves the payment of bonuses from time to time to the Company's employees, including its executive officers, as an incentive to influence employees to be productive over the course of each fiscal year. The determination of which executive officers should receive a bonus and what the amount of the bonus should be is based upon a subjective analysis of the executive's level of responsibility, performance of duties and attainment of performance goals, and also takes into consideration other types and amounts of compensation paid to the executive, such as commissions.

Long-term Stock Ownership Plans. During the 2002 fiscal year the Company had several active stock plans in place for employees, officers and directors, including the 1998 STAAR Surgical Company Stock Plan,

the 1996 STAAR Surgical Company Non-Qualified Stock Plan, the 1991 Stock Option Plan of STAAR Surgical Company and the STAAR Surgical Company Stock Option Plan and Agreement for Chief Executive Officer. From time to time the Company has also issued non-qualified options that were not part of a formal plan. With the exception of the 1996 STAAR Surgical Company Non-Qualified Stock Plan and non-qualified options issued that were not part of a formal plan, the stockholders of the Company have approved these plans. The plans afford the Company the ability to make stock grants and to grant incentive stock options, non-qualified stock options, and stock appreciation rights to, among others, the Company's directors, officers and employees.

The Compensation Committee's objective is to grant stock or options to purchase stock under its stock plans subject to vesting conditions based on continued employment. These vesting requirements are intended to create a more productive workforce by acting as an inducement for long-term employment with the Company, thereby lending stability to our employee base and encouraging more long-term productivity by our employees as they see their efforts translate into greater share value.

Compensation for Chief Executive Officer. Mr. Bailey's compensation is described in the section of this Annual Report entitled "Employment Agreements with Named Executive Officers." Mr. Bailey's base compensation of \$350,000 was based upon competitive market forces, his extensive experience in the ophthalmic products industry and his successful management of the surgical division of CIBA Vision Corporation, a private company with over \$1 billion in revenues.

During the 2002 fiscal year, the Compensation Committee recommended, and the Board of Directors approved, the grant of an option to Mr. Bailey allowing him to purchase 150,000 shares of the Company's Common Stock at \$3.81 per share (exercise price is the fair market value of the Common Stock on the date of grant). These options became fully vested upon Mr. Bailey's achievement of certain goals established by the Compensation Committee. These goals included: the attainment of positive cash flow, the hiring of key executives, the launch of a product line in Germany and other key international markets, and the approval of the U.S. FDA of an investigational device exemption for the Toric ICL.

In addition to his compensation as Chief Executive Officer, Mr. Bailey is entitled to stock options upon reelection to the Board of Directors. Accordingly, on May 30, 2002, Mr. Bailey received options to purchase 60,000 shares of our Common Stock at an exercise price of \$5.19. These options vest in three equal amounts of 20,000 shares during each year of service with the first vesting on the date of grant.

Policy under §162(m) of the Internal Revenue Code. The Compensation Committee has not formulated a policy in qualifying compensation paid to executive officers for deductibility under Section 162(m) of the Internal Revenue Code, and does not foresee the necessity of doing so in the near future. Should limitations on the deductibility of compensation become a material issue, the Compensation Committee will, at such time, determine whether such a policy should be implemented, either in general or with respect to specific transactions.

The Compensation Committee

John Gilbert

Dr. Volker D. Anhaeusser

David Morrison

STOCK PERFORMANCE GRAPH

Set forth below is a line graph, assuming an initial investment of \$100 on December 31, 1997, comparing the yearly percentage change in the cumulative total stockholder return for the last five fiscal years of the Common Stock relative to the cumulative total stockholder return for the same time period of: (i) United States and foreign companies listed on the Nasdaq Stock Market (the Nasdaq Index); and (ii) United States and foreign companies listed on the Nasdaq Stock Market (the Peer Index) which operate in the surgical, medical and dental instrument and supply industries (based upon Standard Industrial Classification (SIC) codes in the range of 3840 through 3849; the Company s SIC code is 3845). The Nasdaq Index and the Peer Index were prepared by the Center for Research in Security Prices of the University of Chicago s Graduate School of Business. The graph is not necessarily indicative of future price performance.

The graph shall not be deemed incorporated by reference by any general statement incorporating by reference to this Annual Report on Form 10-K into any filing under the Securities Act or under the Exchange Act, except to the extent that the Company specifically incorporates this information by reference, and shall not otherwise be deemed filed under such Acts.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The following table sets forth each beneficial owner (other than directors and named executive officers) of more than 5% of our Common Stock. This information is based on publicly available information filed with the Securities and Exchange Commission as of May 8, 2003.

| Name and Address of Beneficial Owners | Number of Shares and Nature of Beneficial Ownership | Percent of Outstanding Common Stock |
|---|---|-------------------------------------|
| Wellington Management Company, LLP 75 State Street Boston, Massachusetts 02109 | 1,450,000(1) | 8.42% |
| Dimensional Fund Advisors Inc. 1299 Ocean Avenue, 11th Floor Santa Monica, CA 90401 | 1,021,950(2) | 5.93% |
| Federated Investors, Inc. Federated Investors Tower 5800 Corporate Drive Pittsburgh, PA 15222 | 1,007,400(3) | 5.9% |

- (1) Shares are as of December 31, 2002 and include 1,090,000 shares with respect to which there is shared power to vote and 1,450,000 shares with respect to which there is shared power of disposition.
- (2) Shares are as of December 31, 2002 and consist of 1,021,950 shares with respect to which the holder has sole voting and dispositive power.
- (3) Shares are as of December 31, 2002 and consist of 1,007,400 shares with respect to which the holder has sole voting and dispositive power.

The following table sets forth, as of May 8, 2003, information with respect to the shares of Common Stock beneficially owned by (i) each director and director nominee; (ii) each person (other than a person who is also a director and/or a director nominee) who is an executive officer named in the Summary Compensation Table below; and (iii) all executive officers and directors as a group. The term executive officer is defined as the President, Chief Financial Officer, any vice-president in charge of a principal business function (such as administration or finance), or any other person who performs similar policy making functions for the Company.

| <u>Beneficial Owner(1)</u> | <u>Shares of Common Stock Beneficially Owned</u> | <u>Rights to Acquire Beneficial Ownership(2)</u> | <u>Total</u> | <u>Percent of Class(3)</u> |
|---|--|--|--------------|--------------------------------|
| David Bailey | 50,754 | 840,000 | 890,754 | 5.2% |
| John Bily | | 33,333 | 33,333 | * |
| John Santos | 5,000 | 103,000 | 108,000 | * |
| Helene Lamielle | | 25,000 | 25,000 | * |
| Nicholas Curtis | 3,000 | | 3,000 | * |
| Volker Anhaeusser | 14,425 | 90,000 | 104,425 | * |
| John R. Gilbert | | 60,000 | 60,000 | * |
| David Morrison | | 80,000 | 80,000 | * |
| Donald Duffy | | | | |
| All current directors and executive officers as a group | 73,179 | 1,231,333 | 1,304,512 | 7.6% |

* Less than 1%.

- (1) The business address of each person named is c/o STAAR Surgical Company, 1911 Walker Avenue, Monrovia, California 91016.
- (2) Calculated pursuant to Rule 13d-3(d)(1) of the Securities Exchange Act of 1934. Under Rule 13d-3(d)(1), shares not outstanding which are subject to options, warrants, rights or conversion privileges exercisable within 60 days are deemed outstanding for the purpose of calculating the number and percentage owned by such person, but not deemed outstanding for the purpose of calculating the percentage owned by each other person listed. The Company believes that each individual or entity named has sole investment and voting power with respect to shares of Common Stock indicated as beneficially owned by them, subject to community property laws, where applicable, except where otherwise noted.
- (3) Based on 17,054,233 shares of Common Stock outstanding on the transfer records as of May 8, 2003.

The following table provides information as of January 3, 2003 on all our equity compensation plans currently in effect.

EQUITY COMPENSATION PLAN INFORMATION

| <u>Plan Category</u> | <u>Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights</u> | <u>Weighted Average Exercise Price</u> | <u>Number of Securities Remaining Available for Future Issuance under Equity Compensation</u> |
|----------------------|--|--|---|
| | | (b) | |

Edgar Filing: STAAR SURGICAL COMPANY - Form 10-K/A

| | (a) | _____ | Plans (excluding securities reflected in column (a)) |
|------------------------------------|------------------|-------------|--|
| | | | (c) |
| | _____ | | _____ |
| Plans Approved by Shareholders | 2,423,165(1) | 7.52 | 407,739(1) |
| Plans Not Approved by Shareholders | 715,150 | 4.64 | 434,329(2) |
| | _____ | | _____ |
| Total Options | 3,138,315 | 6.86 | 842,068 |
| | _____ | | _____ |

(1) Represents awards issued under the 1991 Stock Option Plan of STAAR Surgical Company, the 1998 STAAR Surgical Company Stock Plan (1998 Plan) and the STAAR Surgical Company Stock Option Plan

and Agreement for Chief Executive Officer. Securities remaining available for issuance are pursuant to the 1998 Plan only.

- (2) Under the terms of the 1995 STAAR Surgical Company Consultant Plan and the 1996 STAAR Surgical Company Non-Qualified Stock Plan, the maximum number of shares which may be issued or granted under the Plan shall be increased by (i) the number of shares or stock rights tendered by a Recipient as payment of Option or Awarded shares; (ii) the number of shares subject to an Option which is terminated unexercised or expires; and (iii) the number of restricted shares granted which are subsequently forfeited by the holders thereof.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

Indebtedness of Management

Peter J. Utrata

As of January 3, 2003, Dr. Peter J. Utrata, one of our directors until January 28, 2003, was indebted to us in the amount of \$1,530,500. Excluding interest, this is the largest aggregate amount of indebtedness owed by Dr. Utrata during 2002. The following table sets forth the date on which each loan was made and the principal amount of the loan:

| <u>Date of Loan</u> | <u>Amount of Loan</u> |
|---------------------|-----------------------|
| June 16, 1999 | \$ 1,258,000 |
| June 2, 2000 | \$ 272,500 |

We received full recourse promissory notes from Dr. Utrata memorializing these loans. The loans were used by Dr. Utrata to exercise options to purchase our Common Stock.

The promissory note in the amount of \$1,258,000 is due to be paid in full on June 15, 2004 and bears interest at the lower of the lowest rate allowable by the Internal Revenue Service without the imputation of interest or 7%. Payment of the promissory note is partly secured with 120,000 shares of our Common Stock, pursuant to the terms of a Stock Pledge Agreement executed by Dr. Utrata.

The promissory note in the amount of \$272,500 is due to be paid in full on June 1, 2005 and bears interest at the lower of the lowest rate allowable by the Internal Revenue Service without the imputation of interest or 7%. Payment of the promissory note is partly secured with 20,000 shares of our Common Stock, pursuant to the terms of a Stock Pledge Agreement executed by Dr. Utrata, as additional security for repayment of this loan.

A promissory note in the amount of \$100,000, plus accrued interest, was paid in full on November 10, 2002. Dr. Utrata resigned as director on January 28, 2003.

John Santos

Edgar Filing: STAAR SURGICAL COMPANY - Form 10-K/A

As of January 3, 2003, Mr. John Santos, one of our executive officers, was indebted to us in the amount of \$74,500. Excluding interest, this is the largest aggregate amount of indebtedness owed by Mr. Santos during 2002. The following table sets forth the date on which each loan was made and the principal amount of the loan:

| <u>Date of Loan</u> | <u>Amount of Loan</u> |
|---------------------|-----------------------|
| July 19, 1996 | \$ 25,000 |
| August 28, 1998 | \$ 30,000 |
| September 8, 1998 | \$ 14,500 |
| April 11, 2001 | \$ 5,000 |

We received full recourse demand notes from Mr. Santos memorializing these loans, which were taken by Mr. Santos as personal loans.

These notes have no set term, and are due at the Company's option upon 60 days written notice. The notes bear interest at rates ranging from 5% to 7%, or the lower of the lowest rate allowable by the Internal Revenue Service without the imputation of interest.

Consulting Agreement

David Morrison

On March 1, 2001, we entered into a Consulting Agreement with DRM Strategic Services Ltd., a private limited company wholly owned by our director, Mr. David Morrison. Pursuant to this Consulting Agreement, we pay DRM Strategic Services Ltd. the sum of \$1,000 for each day Mr. Morrison performs duties as a consultant, but in no month is DRM Strategic Services Ltd. paid for less than six days work. In conjunction with this Consulting Agreement, we issued to Mr. Morrison an option to purchase 20,000 shares of our Common Stock. The option exercise price is \$3.99, the closing price on the date of grant. The duties that Mr. Morrison performs on behalf of DRM Strategic Services Ltd. include performing market research on behalf of the Company, assisting the Company in identifying licensing and co-marketing opportunities throughout the world and assisting the Company with identifying and building strategic relationships within the worldwide ophthalmic industry.

Purchase Agreement

Guenther Roepstorff

During the 2002 fiscal year, we entered into a purchase agreement with Mr. Guenther Roepstorff to acquire the remaining 20% interest in our 80% owned German subsidiary, Domilens GmbH. Pursuant to this agreement, the Company acquired the remaining shares in a non-cash transaction at its book value of \$426,000 in exchange for cancellation of amounts due from Mr. Roepstorff of \$955,000 less bonuses due to Mr. Roepstorff of \$87,000, resulting in goodwill of \$442,000. The terms of the agreement also provided for the cancellation of 75,000 unexercised stock options previously issued to Mr. Roepstorff, the subsidiary's president, and also included an agreement not to compete with the Company for a period of ten years.

ITEM 14. CONTROLS AND PROCEDURES.

(a) Evaluation of disclosure controls and procedures.

Within the 90 days prior to the filing date of this report, the Chief Executive Officer and the Chief Financial Officer of the Company, with the participation of the Company's management, carried out an evaluation of the effectiveness of the Company's disclosure controls and procedures pursuant to Exchange Act Rule 13a-14. Based upon that evaluation, the Chief Executive Officer and the Chief Financial Officer believe that, as of the date of the evaluation, the Company's disclosure controls and procedures are effective in making known to them material information relating to the Company (including its consolidated subsidiaries) required to be included in this report.

Disclosure controls and procedures, no matter how well designed and implemented, can provide only reasonable assurance of achieving an entity's disclosure objectives. The likelihood of achieving such objectives is affected by limitations inherent in disclosure controls and procedures. These include the fact that human judgment in decision-making can be faulty and that breakdowns in internal control can occur because of human failures such as simple errors or mistakes or intentional circumvention of the established process.

(b) Changes in internal controls.

There were no significant changes in the Company's internal controls or in other factors that could significantly affect internal controls, known to the Chief Executive Officer or the Chief Financial Officer, subsequent to the date of the evaluation.

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES, AND REPORTS ON FORM 8-K.

| | Page |
|---|-------------|
| (a)(1) Financial statements required by Item 14 of this form are filed as a separate part of this report following Part IV | |
| Report of Independent Certified Public Accountants | F-2 |
| Consolidated Balance Sheets at January 3, 2003 and December 28, 2001 | F-3 |
| Consolidated Statements of Operations for the years ended January 3, 2003, December 28, 2001, and December 29, 2000 | F-4 |
| Consolidated Statements of Changes in Stockholders' Equity and Comprehensive Loss for the years ended January 3, 2003, December 28, 2001, and December 29, 2000 | F-5 |
| Consolidated Statements of Cash Flows for the years ended January 3, 2003, December 28, 2001, and December 29, 2000 | F-6 |
| Notes to Consolidated Financial Statements | F-13 |

(2) Schedules required by Regulation S-X are filed as an exhibit to this report:

Edgar Filing: STAAR SURGICAL COMPANY - Form 10-K/A

I. Independent Certified Public Accountants Report on Schedule

II. Independent Certified Public Accountants Consent

III. Valuation and Qualifying Accounts and Reserves

Schedules not listed above have been omitted because the information required to be set forth therein is not applicable or is shown in the financial statements and the notes thereto.

(3) *Reports on Form 8-K*

On December 6, 2002 the Company filed a Current Report on Form 8-K disclosing the Settlement Agreement and Mutual General Release entered into between the Company and John R. Wolf the former Chief Executive Officer of the Company.

On March 31, 2003 the Company filed a Current Report on Form 8-K reporting that the Company and Wells Fargo Bank executed an agreement on March 26, 2003, extending the maturity date of the Company's \$3.0 million line-of-credit for one year to March 31, 2004.

(4) *Exhibits*

- 3.1 Certificate of Incorporation, as amended(8)
- 3.2 By-laws, as amended(9)
 - 4.1 1990 Stock Option Plan(1)
 - 4.2 1991 Stock Option Plan(2)
 - 4.3 1995 STAAR Surgical Company Consultant Stock Plan(3)
 - 4.4 1996 STAAR Surgical Company Non-Qualified Stock Plan(4)
 - 4.5 Stockholders' Rights Plan, dated effective April 20, 1995(9)
 - 4.6 1998 STAAR Surgical Company Stock Plan, adopted April 17, 1998(5)
- 10.1 Joint Venture Agreement, dated May 23, 1988, between the Company, Canon Sales Co, Inc. and Canon, Inc.(7)
- 10.2 Promissory Note dated February 28, 1991, from John R. Wolf to the Company(4)
- 10.3 Stock Pledge/Security Agreement, dated February 28, 1991, between John R. Wolf, the Company and Pollet & Associates(4)
- 10.4 Promissory Note dated February 28, 1991, from William C. Huddleston to the Company(4)
- 10.5 Modification dated August 21, 2000 to Promissory Note dated February 28, 1991, from William C. Huddleston to the Company(9)
- 10.6 Stock Pledge/Security Agreement, dated February 28, 1991, between William C. Huddleston, the Company and Pollet & Associates(4)
- 10.7 Promissory Note, dated May 26, 1992, from the Andrew F. Pollet and Sally M. Pollet Revocable Trust dated March 6, 1990(6)
- 10.8 Deed of Trust, dated September 21, 1992, by the Andrew F. Pollet and Sally M. Pollet Revocable Trust dated March 6, 1990(6)
- 10.9 Promissory Note dated July 3, 1992, from William C. Huddleston to the Company(6)
- 10.10 Modification dated August 21, 2000, to Promissory Note dated July 3, 1992, from William C. Huddleston to the Company(9)
- 10.11 Stock Pledge/Security Agreement dated July 3, 1992, between William C. Huddleston the Company and Pollet & Associates(6)
- 10.12 Lease, dated November 9, 1992, by and between Linda Lee Brown and Phyllis Ann Bailey and the Company regarding real property located at 1911 Walker Avenue, Monrovia, California(6)
- 10.13 Indenture of Lease dated September 1, 1993, between the Company and FKT Associates(9)
- 10.14 Second Amendment to Indenture of Lease dated September 21, 1998, between the Company and FKT Associates(9)

- 10.15 Indenture of Lease dated October 20, 1983, between Dale E. Turner and Francis R. Turner(6)
- 10.16 Promissory Note dated March 18, 1993, from William C. Huddleston to the Company(9)
- 10.17 Modification dated August 21, 2000 to Promissory Note dated March 18, 1993, from William C. Huddleston to the Company(9)
- 10.18 Patent License Agreement, dated May 24, 1995, with Eye Microsurgery Intersectoral Research and Technology Complex(9)
- 10.19 Patent License Agreement, dated January 1, 1996, with Eye Microsurgery Intersectoral Research and Technology Complex(9)
- 10.20 Agreement dated December 31, 1997, between the Company and Mentor Corporation(7)
- 10.21 Promissory Note dated September 4, 1998, from John R. Wolf to the Company(7)
- 10.22 Stock Pledge Agreement, dated September 4, 1998, between the Company and John R. Wolf(7)
- 10.23 Stock Pledge Agreement dated September 4, 1998, between the Company and William C. Huddleston(7)
- 10.24 Promissory Note dated September 4, 1998, from Andrew F. Pollet to the Company(7)
- 10.25 Stock Pledge Agreement dated September 4, 1998, between the Company and Andrew F. Pollet(7)
- 10.26 License and Supply Agreement dated May 6, 1999, between LensTec Incorporated, Lenstec Barbados Inc., STAAR Surgical AG and the Company(8)
- 10.27 Equipment Purchase and Sale Agreement dated May 6, 1999, between Lenstec, Incorporated and the Company(8)
- 10.28 Employment Agreement dated April 28, 1999, between the Company and John Santos(9)
- 10.29 Modification to Employment Agreement dated May 31, 2000, between the Company and John Santos(9)
- 10.30 Second Modification to Employment Agreement dated September 5, 2000, between the Company and John Santos(9)
- 10.31 Promissory Note dated June 16, 1999, from Peter J. Utrata, M.D. to the Company(8)
- 10.32 Stock Pledge Agreement dated June 16, 1999, by Peter J. Utrata, M.D. in favor of the Company(8)
- 10.33 Promissory Note dated November 11, 1999, from Peter J. Utrata, M.D. to the Company(8)
- 10.34 Promissory Note dated November 12, 1999, from John R. Wolf to the Company(8)
- 10.35 Promissory Note dated November 17, 1999, from William C. Huddleston to the Company(8)
- 10.36 Standard Industrial/Commercial Multi-Tenant Lease-Gross dated April 5, 2000, entered into between the Company and Kilroy Realty, L.P.(9)
- 10.37 Promissory Note dated April 7, 2000, from William C. Huddleston to the Company(9)
- 10.38 Modification dated August 21, 2000, to Promissory Note dated April 7, 2000, from William C. Huddleston to the Company(9)
- 10.39 Description of oral agreement between John R. Wolf and the Company dated April 18, 2000(9)
- 10.40 Promissory Note dated June 2, 2000, from Peter J. Utrata, M.D. to the Company(9)
- 10.41 Stock Pledge Agreement dated June 2, 2000, between the Company and Peter J. Utrata, M.D.(9)
- 10.44 Promissory Note dated September 5, 2000, from Andrew F. Pollet to the Company(9)
- 10.45 Deed of Trust dated September 5, 2000, against real property commonly known as 10934 Alto Court, Oak View, California executed in favor of the Company by Andrew F. Pollet and Sally M. Pollet, as individuals and as trustees of the Andrew F. and Sally M. Pollet Revocable Trust dated March 6, 1990(9)

- 10.47 Form of Purchase Agreement entered into between the Company and Fortis Advantage Portfolios, Inc. Capital Appreciation Portfolio(9)
- 10.48 Form of Purchase Agreement entered into between the Company and Fortis Series Fund, Inc. Aggressive Growth Series(9)
- 10.49 Form of Purchase Agreement entered into between the Company and Phoenix Edge Series Fund Engemann Small & Mid Cap Growth Series(9)
- 10.50 Form of Purchase Agreement entered into between the Company and Phoenix-Engemann Small Cap Fund(9)
- 10.51 Form of Purchase Agreement entered into between the Company and Phoenix-Engemann Small & Mid-Cap Growth Fund(9)
- 10.52 Form of Purchase Agreement entered into between the Company and Pequot Scout Fund, L.P.(9)
- 10.53 Form of Purchase Agreement entered into between the Company and Pequot Navigator Offshore Fund, Inc.(9)
- 10.54 Form of Purchase Agreement entered into between the Company and Baystar International, Ltd.(9)
- 10.55 Form of Purchase Agreement entered into between the Company and Baystar Capital, L.P.(9)
- 10.56 Form of Purchase Agreement entered into between the Company and Invesco Global Health Sciences Fund(9)
- 10.57 Promissory Note dated October 23, 2000, from Andrew F. Pollet to the Company(9)
- 10.59 Letter Agreement between the Company and Wells Fargo Bank, National Association and Revolving Line of Credit Note(9)
- 10.60 Promissory Note dated November 1, 2000, from Andrew F. Pollet to the Company(9)
- 10.61 Settlement Agreement and Mutual Release dated December 19, 2000, between the Company and William C. Huddleston(9)
- 10.62 Employment Agreement dated December 20, 2000, between the Company and David Bailey(9)
- 10.63 Stock Option Agreement dated December 20, 2000, between the Company and David Bailey(9)
- 10.64 Letter Amendment dated December 22, 2000, between the Company and Wells Fargo Bank, N. A.(10)
- 10.65 Consulting Agreement dated March 1, 2001, between the Company and DRM Strategic Services, Ltd.(10)
- 10.66 Letter Agreement dated April 1, 2001, between the Company and Wells Fargo Bank, N.A.(10)
- 10.67 Letter Amendment dated July 1, 2001, between the Company and Wells Fargo Bank, N.A.(10)
- 10.68 Letter Agreement dated July 1, 2001, between the Company and Wells Fargo Bank, N.A.(10)
- 10.69 Severance and Release Agreement dated August 21, 2001, between the Company and Thomas J. Chambers (including Consulting Agreement dated August 9, 2001)(10)
- 10.70 Settlement Agreement between the Company, Canon, Inc., Canon Sales Co., Inc., and Canon-STAAR Co. Inc. dated September 28, 2001(10)
- 10.71 Fifth Amendment to Credit Agreement dated October 1, 2001, between the Company and Wells Fargo Bank, N.A.(10)
- 10.72 Settlement and Release Agreement dated October 5, 2001, between the Company and Gunther Roepstorff(10)
- 10.73 Stock Option Agreement dated November 13, 2001, between the Company and David Bailey(10)
- 10.74 Stock Option Agreement dated November 13, 2001, between the Company and David R. Morrison(10)

| | |
|----------|---|
| 10.75 | Stock Option Certificate dated November 13, 2001, between the Company and Richard D. Simmons(10) |
| 10.76 | Sixth Amendment to Credit Agreement dated December 20, 2001, between the Company and Wells Fargo Bank, N.A.(10) |
| 10.77 | Letter Agreement dated January 25, 2002, between the Company and Wells Fargo Bank, N.A.(10) |
| 10.78 | Second Amendment to the Amended and Restated Credit Agreement dated October 25, 2002, between the Company and Wells Fargo Bank, N.A.(12) |
| 10.79 | Settlement Agreement and Mutual General Release between John R. Wolf and the Company dated November 12, 2002(13) |
| 10.80 | Employment Agreement dated January 3, 2002, between the Company and John Bily(11) |
| 10.81 | Employment Agreement dated January 22, 2002, between the Company and Helene Lamielle(11) |
| *10.82 | Master Credit Agreement dated December 15, 2000, between STAAR Surgical AG and UBS AG |
| *#10.83 | Amended and Restated Credit Agreement dated March 29, 2002, between the Company and Wells Fargo Bank |
| * 10.84 | Settlement Agreement and General Release dated March 29, 2002, among the Company, Sally M. Pollet, Pollet and Richardson, and the Estate of Andrew F. Pollet |
| * 10.85 | Settlement Note dated March 29, 2002, from Sally M. Pollet to the Company |
| * #10.86 | Stock Pledge Agreement dated March 29, 2002, between the Company and Sally M. Pollet |
| * 10.87 | Promissory Note dated March 29, 2002 from, Pollet & Richardson to the Company |
| * #10.88 | Security Agreement dated March 29, 2002, between the Company and Pollet & Richardson |
| *#10.89 | First Amendment to the Amended and Restated Credit Agreement dated July 31, 2002, between the Company and Wells Fargo Bank. |
| *10.90 | Third Amendment to the Amended and Restated Credit Agreement dated November 25, 2002, between the Company and Wells Fargo Bank, N.A. |
| *#10.91 | Assignment Agreement of the Share Capital of Domilens Vertrieb fuer medizinische Produkte GmbH dated January 3, 2003, between Staar Surgical AG and Guenther Roepstorff |
| *10.92 | Credit Agreement effective January 13, 2003, between Domilens GmbH and Postbank. |
| *10.93 | Settlement Agreement and Mutual General Release dated February 27, 2003, by and between the Company and Richard Leza |
| *10.94 | Waiver of Certain Covenant Violations dated February 27, 2003, between the Company and Wells Fargo Bank |
| #10.95 | Second Amended and Restated Credit Agreement dated March 26, 2003, between the Company and Wells Fargo Bank(14) |
| *21. | List of Significant Subsidiaries |
| **09.1 | Certification Pursuant to 18 U.S.C. Section 1350 as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 |

** Filed herewith

* Previously filed with this Report on April 3, 2003

Management contract or compensatory plan or arrangement

All schedules and or exhibits have been omitted. Any omitted schedule or exhibit will be furnished supplementally to the Securities and Exchange Commission upon request

(1) Incorporated by reference from the Company's Registration Statement on Form S-8, File No. 033-37248, as filed on October 11, 1990.

(2) Incorporated by reference from the Company's Registration Statement on Form S-8, File No. 033-76404, as filed on March 11, 1994.

- (3) Incorporated by reference from the Company's Registration Statement on Form S-8, File No. 033-60241, as filed on June 15, 1995.
- (4) Incorporated by reference from the Company's Annual Report on Form 10-K, File No. 0-11634, for the year ended January 3, 1997, as filed on April 2, 1997.
- (5) Incorporated by reference from the Company's Proxy Statement, File No. 0-11634, for its Annual Meeting of Stockholders held on May 29, 1998, as filed on May 4, 1999.
- (6) Incorporated by reference from the Company's Annual Report on Form 10-K, File No. 0-11634, for the year ended January 1, 1998, as filed on April 1, 1998.
- (7) Incorporated by reference from the Company's Annual Report on Form 10-K, File No. 0-11634, for the year ended January 1, 1999, as filed on April 1, 1999.
- (8) Incorporated by reference from the Company's Annual Report on Form 10-K, File No. 0-11634, for the year ended December 31, 1999, as filed on March 30, 2000.
- (9) Incorporated by reference from the Company's Annual Report on Form 10-K, File No. 0-11634, for the year ended December 29, 2000, as filed on March 29, 2001.
- (10) Incorporated by reference to the Company's Annual Report on Form 10-K, File No. 0-11634, for the year ended December 28, 2001, as filed on March 28, 2002.
- (11) Incorporated by reference to the Company's Quarterly Report, File No. 0-11634, for the period ended June 28, 2002, as filed on August 12, 2002.
- (12) Incorporated by reference to the Company's Quarterly Report, File No. 0-11634, for the period ended September 27, 2002, as filed on November 12, 2002.
- (13) Incorporated by reference to the Company's Current Report on Form 8-K, File No. 0-11634, filed on December 6, 2002.
- (14) Incorporated by reference to the Company's Current Report on Form 8-K, File No. 0-11634, filed on March 31, 2003.

Certifications

I, David Bailey, certify that:

1. I have reviewed this Amendment No. 3 to the annual report on Form 10-K of STAAR Surgical Company;

2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report;

3. Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this annual report;

4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and have:
 - a) designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;

 - b) evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this annual report (the "Evaluation Date"); and

 - c) presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;

5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):
 - a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and

 - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and

Edgar Filing: STAAR SURGICAL COMPANY - Form 10-K/A

6. The registrant's other certifying officers and I have indicated in this annual report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: November 19, 2003

By: /s/ DAVID BAILEY

David Bailey

President, Chief Executive Officer, Chairman and

Director (principal executive officer)

58

Certifications

I, John Bily, certify that:

1. I have reviewed this Amendment No. 3 to the annual report on Form 10-K of STAAR Surgical Company;
2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report;
3. Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this annual report;
4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and have:
 - a. designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;
 - b. evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this annual report (the "Evaluation Date"); and
 - c. presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;
5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):
 - a. all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and
 - b. any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and

Edgar Filing: STAAR SURGICAL COMPANY - Form 10-K/A

6. The registrant's other certifying officers and I have indicated in this annual report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: November 19, 2003

By: /s/ JOHN BILY

John Bily

Chief Financial Officer

(principal accounting and financial officer)

STAAR SURGICAL COMPANY AND SUBSIDIARIES

CONSOLIDATED FINANCIAL STATEMENTS

YEARS ENDED JANUARY 3, 2003,

DECEMBER 28, 2001 AND DECEMBER 29, 2000

REPORT OF INDEPENDENT CERTIFIED PUBLIC ACCOUNTANTS

Board of Directors

STAAR Surgical Company

We have audited the accompanying restated consolidated balance sheets of STAAR Surgical Company and subsidiaries as of January 3, 2003 and December 28, 2001, and the related restated consolidated statements of operations, stockholders' equity and comprehensive loss, and cash flows for each of the three years in the period ended January 3, 2003. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the restated consolidated financial statements referred to above present fairly, in all material respects, the financial position of STAAR Surgical Company and subsidiaries as of January 3, 2003 and December 28, 2001, and the results of their operations and their cash flows for each of the three years in the period ended January 3, 2003, in conformity with accounting principles generally accepted in the United States of America.

As discussed in the Summary of Accounting Policies to the restated consolidated financial statements, effective December 29, 2001, STAAR Surgical Company and subsidiaries adopted the provisions of SFAS No. 142, Goodwill and Other Intangible Assets.

/s/ BDO SEIDMAN, LLP

Los Angeles, California

February 21, 2003

(except for Note 18 which is dated March 26, 2003 and Notes 6 and 19 which are dated November 17, 2003)

STAAR SURGICAL COMPANY AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS

January 3, 2003 and December 28, 2001

| | 2002 | 2001 |
|--|---|-----------------|
| | Restated | Restated |
| | (In thousands, except par value amounts) | |
| ASSETS | | |
| Current assets: | | |
| Cash and cash equivalents | \$ 1,009 | \$ 853 |
| Restricted cash | | 2,000 |
| Accounts receivable, less allowance for doubtful accounts | 5,992 | 7,542 |
| Inventories | 11,761 | 15,231 |
| Prepays, deposits and other current assets | 2,510 | 3,660 |
| Deferred income tax, current | | 5,304 |
| | <hr/> | <hr/> |
| Total current assets | 21,272 | 34,590 |
| | <hr/> | <hr/> |
| Investment in joint venture | 462 | 466 |
| Property, plant and equipment, net | 7,438 | 8,742 |
| Patents and licenses, net of accumulated amortization of \$4,967 and \$4,034 | 9,038 | 9,896 |
| Goodwill | 6,427 | 5,985 |
| Deferred income tax, non-current | | 3,828 |
| Other assets | 583 | 1,143 |
| | <hr/> | <hr/> |
| Total assets | \$ 45,220 | \$ 64,650 |
| | <hr/> | <hr/> |
| LIABILITIES AND STOCKHOLDERS EQUITY | | |
| Current liabilities: | | |
| Notes payable | \$ 5,845 | \$ 8,216 |
| Accounts payable | 4,556 | 5,594 |
| Other current liabilities | 4,079 | 4,000 |
| | <hr/> | <hr/> |
| Total current liabilities | 14,480 | 17,810 |
| Other long-term liabilities | 89 | 316 |
| | <hr/> | <hr/> |
| Total liabilities | 14,569 | 18,126 |
| | <hr/> | <hr/> |
| Minority interest | 100 | 382 |
| | <hr/> | <hr/> |
| Commitments and contingencies | | |
| Stockholders' equity: | | |
| Preferred stock, \$.01 par value, 10,000 shares authorized, none issued | | |

Edgar Filing: STAAR SURGICAL COMPANY - Form 10-K/A

| | | |
|--|------------------|------------------|
| Common stock, \$.01 par value; 30,000 shares authorized; issued and outstanding 17,205 and 17,158 shares | 172 | 172 |
| Additional paid-in capital | 75,947 | 75,573 |
| Accumulated other comprehensive loss | (111) | (1,728) |
| Accumulated deficit | (40,789) | (24,011) |
| | <u>35,219</u> | <u>50,006</u> |
| Treasury stock, at cost (243 and 0 shares) | (973) | |
| | <u>34,246</u> | <u>50,006</u> |
| Notes receivable from officers and directors | (3,695) | (3,864) |
| | <u>30,551</u> | <u>46,142</u> |
| Total stockholders' equity | | |
| | <u>\$ 45,220</u> | <u>\$ 64,650</u> |

See accompanying summary of accounting policies and notes to consolidated financial statements.

STAAR SURGICAL COMPANY AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF OPERATIONS

Years Ended January 3, 2003, December 28, 2001 and December 29, 2000

| | 2002 Restated | 2001 Restated | 2000 Restated |
|--|---------------------------|------------------|------------------|
| | (In thousands, | | |
| | except per share amounts) | | |
| Sales | \$ 47,880 | \$ 50,237 | \$ 53,986 |
| Royalty and other income | 368 | 549 | 448 |
| Total revenues | 48,248 | 50,786 | 54,434 |
| Cost of sales | 24,099 | 28,203 | 26,329 |
| Gross profit | 24,149 | 22,583 | 28,105 |
| Selling, general and administrative expenses: | | | |
| General and administrative | 8,959 | 8,746 | 8,593 |
| Marketing and selling | 16,833 | 20,043 | 21,254 |
| Research and development | 4,016 | 3,800 | 4,215 |
| Other charges | 1,454 | 7,780 | 15,276 |
| Total selling, general and administrative expenses | 31,262 | 40,369 | 49,338 |
| Operating loss | (7,113) | (17,786) | (21,233) |
| Other income (expense): | | | |
| Equity in operations of joint venture | 36 | 389 | (4,698) |
| Interest income | 361 | 1 | 826 |
| Interest expense | (579) | (640) | (1,496) |
| Other income (expense) | (603) | (474) | 738 |
| Total other expense, net | (785) | (724) | (4,630) |
| Loss before income taxes and minority interest | (7,898) | (18,510) | (25,863) |
| Provision (benefit) for income taxes | 8,805 | (3,649) | (6,758) |
| Minority interest | 75 | 139 | 87 |
| Net loss | \$ (16,778) | \$ (15,000) | \$ (19,192) |
| Loss per share: | | | |
| Basic and diluted | \$ (0.98) | \$ (0.88) | \$ (1.25) |

See accompanying summary of accounting policies and notes to consolidated financial statements.

F-4

Edgar Filing: STAAR SURGICAL COMPANY - Form 10-K/A

Foreign currency translation

adjustment

Net loss (16,778) (16,778)

Balance, at January 3, 2003 \$ 172 \$ 75,947 \$ (111) \$ (40,789) \$ (973) \$ (3,695) \$ 30,551

See accompanying summary of accounting policies and notes to consolidated financial statements.

STAAR SURGICAL COMPANY AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS

Years Ended January 3, 2003, December 28, 2001 and December 29, 2000

| | <u>2002</u> <u>Restated</u> | <u>2001</u> <u>Restated</u> | <u>2000</u> <u>Restated</u> |
|---|--------------------------------|--------------------------------|--------------------------------|
| (In thousands) | | | |
| Cash flows from operating activities: | | | |
| Net loss | \$ (16,778) | \$ (15,000) | \$ (19,192) |
| Adjustments to reconcile net loss to net cash provided by (used in) operating activities: | | | |
| Depreciation of property and equipment | 2,171 | 2,364 | 2,140 |
| Amortization of intangibles | 933 | 1,259 | 1,590 |
| Write-off of accounts receivable | | | 449 |
| Deferred revenue | | | (448) |
| Equity in operations of joint venture | (36) | (746) | 3,577 |
| Deferred income taxes | 9,132 | (4,537) | (6,810) |
| Stock-based compensation expense | 236 | 53 | |
| Common stock issued for services | 132 | 413 | 1,224 |
| Non-cash restructuring and inventory write-down | 1,225 | 13,230 | 18,029 |
| Other | (226) | 269 | 468 |
| Minority interest | 144 | 178 | (332) |
| Changes in working capital: | | | |
| Accounts receivable | 1,462 | 1,697 | (759) |
| Inventories | 3,108 | (1,316) | (4,020) |
| Prepays, deposits and other current assets | (232) | 2,619 | (301) |
| Accounts payable | (966) | (573) | (1,249) |
| Other current liabilities | 264 | (2,450) | 605 |
| | <u>569</u> | <u>(2,540)</u> | <u>(5,029)</u> |
| Cash flows from investing activities: | | | |
| Acquisition of property and equipment | (874) | (1,180) | (3,339) |
| Acquisition of patents and licenses | (75) | (245) | (775) |
| Proceeds from notes receivable and other | 10 | 321 | 789 |
| Change in other assets | 493 | 119 | (817) |
| Dividends received from joint venture | 40 | 280 | |
| | <u>(406)</u> | <u>(705)</u> | <u>(4,142)</u> |
| Cash flows from financing activities: | | | |
| Net borrowings (payments) under notes payable and long-term debt | (2,598) | 276 | 414 |
| Payments on notes payable and long-term debt | | | (9,400) |
| Restricted cash | 2,000 | (2,000) | |
| Proceeds from the exercise of stock options and warrants | 6 | 63 | 2,520 |
| Proceeds from private placement | | | 18,681 |
| | <u>(592)</u> | <u>(1,661)</u> | <u>12,215</u> |

Edgar Filing: STAAR SURGICAL COMPANY - Form 10-K/A

| | | | |
|--|-------------------|-------------------|-------------------|
| Effect of exchange rate changes on cash and cash equivalents | 585 | (328) | (301) |
| | <u> </u> | <u> </u> | <u> </u> |
| Increase (decrease) in cash and cash equivalents | 156 | (5,234) | 2,743 |
| Cash and cash equivalents, at beginning of year | 853 | 6,087 | 3,344 |
| | <u> </u> | <u> </u> | <u> </u> |
| Cash and cash equivalents, at end of year | \$ 1,009 | \$ 853 | \$ 6,087 |
| | <u> </u> | <u> </u> | <u> </u> |

See accompanying summary of accounting policies and notes to consolidated financial statements.

STAAR SURGICAL COMPANY AND SUBSIDIARIES

SUMMARY OF ACCOUNTING POLICIES

Years Ended January 3, 2003, December 28, 2001 and December 29, 2000

Organization and Description of Business

STAAR Surgical Company (the Company), a Delaware corporation, was incorporated in 1982 for the purpose of developing, producing, and marketing Intraocular Lenses (IOLs) and other products for minimally invasive ophthalmic surgery. The Company has evolved to become a developer, manufacturer and global distributor of products used by ophthalmologists and other eye care professionals to improve or correct vision in patients with refractive conditions, cataracts and glaucoma. Products manufactured by the Company for use in correcting refractive conditions such as myopia (near-sightedness), hyperopia (far-sightedness) and astigmatism include the Implantable Contact Lens (ICL), the Toric ICL (TICL) and the Toric IOL. Products manufactured by the Company for use in restoring vision adversely affected by cataracts include its line of IOLs, the SonicWAVE Phacoemulsification System, STAARVISC II, a viscoelastic material and the UltraVac V1 tubing, used with certain Venturi-type Phacoemulsification machines. The Company's AquaFlowCollagen Glaucoma Drainage Device is surgically implanted in the outer tissues of the eye to maintain a space that allows increased drainage of intraocular fluid thereby reducing intraocular pressure, which may lead to deterioration of vision in patients with glaucoma. The Company also sells other instruments, devices and equipment that are manufactured either by the Company or by others in the ophthalmic products industry.

The Company's most significant subsidiary is STAAR Surgical AG, a wholly owned subsidiary formed in Switzerland to develop, manufacture and distribute certain of the Company's products worldwide, including the ICL and its AquaFlow Device. STAAR Surgical AG also controls a major European sales subsidiary that distributes both the Company's products and products from various other manufacturers. Investment in the subsidiary was increased from 80% to 100% during the fourth quarter of 2002, when Staar Surgical AG purchased the remaining shares of the subsidiary (see Note 17).

Basis of Presentation

The accompanying consolidated financial statements include the accounts of the Company, its wholly and its majority owned subsidiaries. All significant intercompany balances and transactions have been eliminated in consolidation. Assets and liabilities of foreign subsidiaries are translated at rates of exchange in effect at the close of the year. Revenues and expenses are translated at the weighted average of exchange rates in effect during the year. The resulting translation gains and losses are deferred and are shown as a separate component of stockholders' equity as accumulated other comprehensive loss. During 2002, 2001 and 2000, the net foreign translation gain (loss) was \$585,000, \$(328,000) and \$(301,000), respectively and net foreign currency transaction loss was \$458,000, \$204,000 and \$182,000, respectively.

Investment in the Japanese joint venture is accounted for using the equity method of accounting except for the nine-months ended September 29, 2001 and the year ended December 28, 2000 when the investment was written off and earnings were recognized on a cash basis (see Note 4).

The Company's fiscal year ends on the Friday nearest December 31 and each of the Company's quarterly reporting periods generally consist of 13 weeks.

Summary of Significant Accounting Policies

Revenue Recognition

In general, the Company supplies foldable IOLs on a consignment basis to customers, primarily ophthalmologists, surgical centers, hospitals and other eye care providers and recognizes sales when the IOLs are

F-7

STAAR SURGICAL COMPANY AND SUBSIDIARIES

SUMMARY OF ACCOUNTING POLICIES

Years Ended January 3, 2003, December 28, 2001 and December 29, 2000

implanted. Sales of all other products, including sales to foreign distributors, are generally recognized upon shipment.

Revenue from license and technology agreements is recorded as income, when earned, according to the terms of the respective agreements.

Income Taxes

The Company recognizes deferred tax assets and liabilities for temporary differences between the financial reporting basis and the tax basis of the Company's assets and liabilities along with net operating loss and credit carryforwards. A valuation allowance is recognized if, based on the weight of available evidence, it is more likely than not that some portion or all of the deferred tax asset may not be realized. The impact on deferred taxes of changes in tax rates and laws, if any, are applied to the years during which temporary differences are expected to be settled and reflected in the financial statements in the period of enactment.

Cash, Cash Equivalents, and Restricted Cash

The Company considers all highly liquid investments purchased with a maturity of three months or less to be cash equivalents. Restricted cash is invested in money market accounts, which mature within one year (see Note 5.)

Inventories

Inventories are stated at the lower of cost, determined on a first-in, first-out basis, or market. Inventory costs are comprised of material, direct labor, and overhead. The Company records inventory provisions, based on a review of forecasted demand and inventory levels.

Property, Plant and Equipment

Property, plant and equipment are recorded at cost. Depreciation on property, plant, and equipment is computed using the straight-line method over the estimated useful lives of the assets, generally ranging from 5 to 10 years. Major improvements are capitalized and minor replacements, maintenance and repairs are charged to expense as incurred.

Goodwill and Other Intangible Assets

Goodwill represents the excess of the purchase price over the fair value of identifiable net assets acquired in business combinations accounted for as purchases. The Company adopted Statement of Financial Accounting Standards, (SFAS) No. 141, Business Combinations, and No. 142, Goodwill and Other Intangible Assets, on December 29, 2001.

Goodwill, which has an indefinite life and was previously amortized on a straight-line basis over the periods benefited, is no longer amortized to earnings but instead is subject to periodic testing for impairment. Intangible assets determined to have definite lives are amortized over their remaining useful lives. Goodwill of a reporting unit is tested for impairment on an annual basis or between annual tests if an event occurs or circumstances change that would reduce the fair value of a reporting unit below its carrying amount. As provided under

STAAR SURGICAL COMPANY AND SUBSIDIARIES
SUMMARY OF ACCOUNTING POLICIES**Years Ended January 3, 2003, December 28, 2001 and December 29, 2000**

SFAS 142, the initial testing of goodwill for possible impairment was completed within the first six months of 2002 and no impairment has been identified. As of January 3, 2003, the carrying value of goodwill was \$6.4 million.

In accordance with SFAS 142, prior period amounts were not restated. The net loss for the years ended December 28, 2001 and December 29, 2000, adjusted for the exclusion of amortization of goodwill, would have been \$375,000 and \$254,000 less than reported and the loss per share would have decreased by \$0.02 and \$0.02, respectively.

The Company also has other intangible assets consisting of patents and licenses, with a gross book value of \$14.0 million and accumulated amortization of \$5.0 million as of January 3, 2003. The Company capitalizes the costs of acquiring patents and licenses as well as the legal costs of successfully defending its rights to these patents. Amortization is computed on the straight-line basis over the estimated useful lives, which are based on legal and contractual provisions, and range from 10 to 20 years. Aggregate amortization expense for amortized other intangible assets was \$933,000, \$884,000 and \$1.3 million for the years ended January 3, 2003, December 28, 2001 and December 29, 2000, respectively.

The weighted average amortization period for other intangible assets is approximately 15 years. The following table shows the estimated amortization expense for these assets for each of the five succeeding years (in thousands):

| | |
|--------------------|-----------------|
| Fiscal Year | |
| 2003 | \$ 676 |
| 2004 | 676 |
| 2005 | 676 |
| 2006 | 676 |
| 2007 | 676 |
| | <hr/> |
| Total | \$ 3,380 |
| | <hr/> |

Impairment of Long-Lived Assets

Intangible and other long lived-assets are reviewed for impairment whenever events such as product discontinuance, plant closures, product dispositions or other changes in circumstances indicate that the carrying amount may not be recoverable. In reviewing for impairment, the Company compares the carrying value of such assets to the estimated undiscounted future cash flows expected from the use of the assets and their eventual disposition. When the estimated undiscounted future cash flows are less than their carrying amount, an impairment loss is recognized equal to the difference between the assets fair value and their carrying value. No impairment was recognized for the year ended January 3, 2003.

The Company adopted SFAS No. 144, Accounting for the Impairment or Disposal of Long-Lived Assets (SFAS 144), which supersedes SFAS 121, Accounting for Long-Lived Assets and for Long-lived Assets to be Disposed of, during the first quarter of 2002. SFAS 144 addresses financial accounting and reporting requirements for the impairment or disposal of long lived-assets. This statement also expands the scope of a discontinued operation to include a component of an entity, and eliminates the current exemption to consolidation when control over a subsidiary is likely to be temporary. The Company's adoption of SFAS 144 did not have a material impact on its financial position or results of operations.

F-9

STAAR SURGICAL COMPANY AND SUBSIDIARIES

SUMMARY OF ACCOUNTING POLICIES

Years Ended January 3, 2003, December 28, 2001 and December 29, 2000

Accounting Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the amounts reported in the financial statements and footnotes thereto. Actual results may materially differ from those estimates.

Fair Value of Financial Instruments

The carrying values reflected in the consolidated balance sheets for cash and cash equivalents, accounts receivable, accounts payable, and notes payable approximate their fair values because of the short maturity of these instruments.

Loss Per Share

The Company presents loss per share data in accordance with the provision of SFAS No. 128, Earnings per Share (SFAS 128), which provides for the calculation of Basic and Diluted earnings per share. Loss per share of common stock is computed by using the weighted average number of common shares outstanding during the period. Common stock equivalents are not included in the determination of the weighted average number of shares outstanding, as they would be antidilutive. For the years ended January 3, 2003, December 28, 2001, and December 29, 2000, 0, 5,000, and 5,000 warrants and 3.1 million, 2.9 million, and 1.9 million options to purchase shares of the Company's common stock, respectively, were outstanding.

Stock Based Compensation

The Company accounts for stock-based compensation in accordance with APB Opinion No. 25, Accounting for Stock Issued to Employees (APB 25), and has adopted the disclosure provisions of SFAS No. 123, Accounting for Stock Based Compensation (SFAS 123). SFAS 123 defines a fair value based method of accounting for an employee stock option or similar equity instrument and encourages all entities to adopt that method of accounting for all of their employee stock compensation plans. However, it also allows an entity to continue to measure compensation cost for those plans using the intrinsic value based method of accounting prescribed by APB 25. If the APB 25 intrinsic value method of accounting is used, SFAS 123 requires pro forma disclosures of net income and earnings per share as if the fair value based method of accounting for stock based compensation had been applied. The Company records expense in an amount equal to the excess of the quoted market price on the grant date over the option price. Such expense is recognized at the grant date for options fully vested. For options with a vesting period, the expense is recognized over the vesting period.

Comprehensive Loss

The Company presents comprehensive losses in its Consolidated Statement of Changes in Stockholders' Equity in accordance with SFAS No. 130, Reporting Comprehensive Income (SFAS 130). Total comprehensive loss includes, in addition to net loss, changes in equity that are excluded from the consolidated statements of operations and are recorded directly into a separate section of stockholders' equity on the consolidated balance sheets.

F-10

STAAR SURGICAL COMPANY AND SUBSIDIARIES
SUMMARY OF ACCOUNTING POLICIES**Years Ended January 3, 2003, December 28, 2001 and December 29, 2000**

Comprehensive loss and its components consist of the following (in thousands):

| | 2002 | 2001 | 2000 |
|---|--------------------|--------------------|--------------------|
| | Restated | Restated | Restated |
| | <u> </u> | <u> </u> | <u> </u> |
| Net loss | \$ (16,778) | \$ (15,000) | \$ (19,192) |
| Foreign currency translation adjustment | 585 | (328) | (301) |
| | <u> </u> | <u> </u> | <u> </u> |
| Comprehensive loss | <u>\$ (16,193)</u> | <u>\$ (15,328)</u> | <u>\$ (19,493)</u> |

Segments of an Enterprise

The Company reports segment information in accordance with SFAS No. 131, Disclosures about Segments of an Enterprise and Related Information, (SFAS 131). Under SFAS 131 all publicly traded companies are required to report certain information about the operating segments, products, services and geographical areas in which they operate and their major customers. While the Company has expanded its marketing focus beyond the cataract market to include the refractive and glaucoma markets, the cataract market remained its primary source of revenues and accordingly operates as one business segment. See Note 15, Geographic and Product Data for geographic information.

Reclassifications

Certain reclassifications have been made to the prior year consolidated financial statements to conform to the 2002 presentation.

New Accounting Pronouncements

In August 2001, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standards (SFAS) No. 143, Accounting for Asset Retirement Obligations. SFAS No. 143 requires the fair value of a liability for an asset retirement obligation to be recognized in the period in which it is incurred if a reasonable estimate of fair value can be made. The associated retirement costs are capitalized as part of the carrying amount of the long-lived asset. SFAS No. 143 is effective for fiscal years beginning after June 15, 2002. The Company's adoption of SFAS No. 143 did not have a material impact on its operations or financial position.

Edgar Filing: STAAR SURGICAL COMPANY - Form 10-K/A

In May 2002, the FASB issued SFAS No. 145, Rescission of FASB Statements No. 4, 44, and 64, Amendment of FASB Statement No. 13, and Technical Corrections. SFAS No. 145 eliminates Statement 4 (and Statement 64, as it amends Statement 4), which requires gains and losses from extinguishments of debt to be aggregated and, if material, classified as an extraordinary item, and thus, also the exception to applying Opinion 30 is eliminated as well. This statement is effective for years beginning after May 2002 for the provisions related to the rescission of Statements 4 and 64, and for all transactions entered into beginning May 2002 for the provision related to the amendment of Statement 13. The Company's adoption of SFAS No. 145 did not have a material impact on its operations or financial position.

In June 2002, the FASB issued SFAS No. 146, Accounting for Costs Associated with Exit or Disposal Activities, which addresses accounting for restructuring and similar costs. SFAS No. 146 supersedes previous accounting guidance, principally Emerging Issues Task Force (EITF) Issue No. 94-3. The Company will adopt the provisions of SFAS No. 146 for restructuring activities initiated after December 31, 2002. SFAS No. 146 requires that the liability for costs associated with an exit or disposal activity be recognized when the liability is incurred. Under EITF No. 94-3, a liability for an exit cost was recognized at the date of a

STAAR SURGICAL COMPANY AND SUBSIDIARIES

SUMMARY OF ACCOUNTING POLICIES

Years Ended January 3, 2003, December 28, 2001 and December 29, 2000

company's commitment to an exit plan. SFAS No. 146 also establishes that the liability should initially be measured and recorded at fair value. Accordingly, SFAS No. 146 may affect the timing of recognizing future restructuring costs as well as the amount recognized.

In November 2002, the FASB issued Interpretation No. 45, *Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness to Others*, an interpretation of FASB Statements No. 5, 57 and 107 and a rescission of FASB Interpretation No. 34, (*FIN 45*). This interpretation elaborates on the disclosures to be made by a guarantor in its interim and annual financial statements about its obligations under guarantees issued. The interpretation also clarifies that a guarantor is required to recognize, at inception of a guarantee, a liability for the fair value of the obligation undertaken. The initial recognition and measurement provisions of the interpretation are applicable to guarantees issued or modified after December 31, 2002 and are not expected to have a material effect on the Company's operations or financial results. The disclosure requirements are effective for financial statements of interim and annual periods ending after December 31, 2002. Significant guarantees that have been entered into by the Company as of January 3, 2003 are disclosed in Note 9 to the consolidated financial statements.

In December 2002, the FASB issued SFAS No. 148, *Accounting for Stock-Based Compensation Transition and Disclosure*, which amends SFAS No. 123, *Accounting for Stock-Based Compensation*. SFAS No. 148 provides alternative methods of transition for a voluntary change to the fair value based method of accounting for stock-based employee compensation. In addition, SFAS No. 148 amends the disclosure requirements of SFAS No. 123 to require more prominent and more frequent disclosures in financial statements of the effects of stock-based compensation. The transition guidance provisions of SFAS No. 148 are effective for fiscal years ending after December 15, 2002. The interim disclosure provisions are effective for financial reports containing condensed financial statements for interim periods beginning after December 15, 2002. The adoption of SFAS No. 148 is not expected to have a material impact on the Company's consolidated balance sheet or results of operations. The Company will provide the interim disclosures required by SFAS No. 148 beginning in the first quarter of 2003.

In January 2003, the FASB issued FASB Interpretation No. 46, *Consolidation of Variable Interest Entities*, an interpretation of Accounting Research Bulletins (*ARB*) No. 51, *Consolidated Financial Statements*, (*FIN 46*). FIN 46 clarifies the application of ARB No. 51 to certain entities in which equity investors do not have the characteristics of a controlling financial interest or do not have sufficient equity at risk for the entity to finance its activities without additional subordinated financial support from other parties. The Company does not believe the adoption of FIN 46 will have a material impact on its financial position or results of operations.

STAAR SURGICAL COMPANY AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Years Ended January 3, 2003, December 28, 2001

NOTE 1 ACCOUNTS RECEIVABLE

Accounts receivable consisted of the following at January 3, 2003 and December 28, 2001 (in thousands):

| | <u>2002</u> | <u>2001</u> |
|--------------------------------------|-----------------|-----------------|
| Domestic | \$ 3,435 | \$ 4,791 |
| Foreign | 3,362 | 3,519 |
| | <u>6,797</u> | <u>8,310</u> |
| Less allowance for doubtful accounts | 805 | 768 |
| | <u>\$ 5,992</u> | <u>\$ 7,542</u> |

NOTE 2 INVENTORIES

Inventories consisted of the following at January 3, 2003 and December 28, 2001 (in thousands):

| | <u>2002</u> | <u>2001</u> |
|-----------------------------------|------------------|------------------|
| Raw materials and purchased parts | \$ 710 | \$ 1,610 |
| Work in process | 798 | 3,252 |
| Finished goods | 10,253 | 10,369 |
| | <u>\$ 11,761</u> | <u>\$ 15,231</u> |

NOTE 3 PROPERTY, PLANT AND EQUIPMENT

Property, plant and equipment consisted of the following at January 3, 2003 and December 28, 2001 (in thousands):

| | <u>2002</u> | <u>2001</u> |
|--|-----------------|-----------------|
| Machinery and equipment | \$ 14,147 | \$ 11,116 |
| Furniture and fixtures | 5,378 | 7,639 |
| Leasehold improvements | 4,577 | 4,480 |
| | <u>24,102</u> | <u>23,235</u> |
| Less accumulated depreciation and amortization | 16,664 | 14,493 |
| | <u>\$ 7,438</u> | <u>\$ 8,742</u> |

Depreciation expense for the years ended January 3, 2003, December 28, 2001 and December 29, 2000 was \$2.2 million, \$2.4 million and \$2.1 million, respectively.

NOTE 4 INVESTMENT IN JOINT VENTURE

The Company owns a 50% equity interest in a joint venture, the CANON-STAAR Company, Inc. (CSC), with Canon Inc. and Canon Sales Co, Inc., together the Canon Companies. The Company sold CSC an exclusive license to manufacture, market and sell the Company's IOL products in Japan. The investment in the Japanese joint venture is accounted for using the equity method of accounting except for the nine-months ended September 29, 2001 and the year ended December 28, 2000 when the Company's investment of \$3.6 million was

STAAR SURGICAL COMPANY AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

written off, due to disputes between the Company and the Canon Companies. During the fourth quarter of fiscal year 2001, the Company executed an agreement with the Canon Companies resolving all claims between the parties and reaffirming the partnering arrangement to manufacture and distribute ophthalmic products based on the Company's technology.

The financial statements of CSC include assets of approximately \$9.1 and \$8.7 million, and liabilities of approximately \$1.7 million and \$1.8 million, as of January 3, 2003 and December 28, 2001, respectively.

The Company's equity in operations of the joint venture is calculated as follows (in thousands):

| | <u>2002</u> | <u>Q4 2001</u> | <u>2000</u> |
|--|---------------|----------------|-------------------|
| Joint venture net income (loss) | \$ (8) | 134 | \$ |
| Equity interest | 50% | 50% | 50% |
| Total joint venture net income (loss) | (4) | 67 | |
| Charge related to write-off of joint venture | | | (4,698) |
| Equity in operations of joint venture | <u>\$ (4)</u> | <u>\$ 67</u> | <u>\$ (4,698)</u> |

The Company received dividend income of \$40,000 during 2002 and \$322,000 in 2001 when it also reversed \$170,000 of excess accrued legal fees upon settlement of the Company's disputes with Canon.

The Company recorded sales of certain IOL products to CSC of approximately \$142,000, \$118,000 and \$344,000 in 2002, 2001 and 2000, respectively.

NOTE 5 NOTES PAYABLE

The Company had a \$7.0 million line of credit with a domestic lender which matured on March 29, 2002, and was amended and restated from time to time during the year ended January 3, 2003. The line of credit, as modified, extends the maturity date to March 31, 2003, included the release of restricted cash in the amount of \$2.0 million in order to pay down the note and provides for monthly decreases in availability through February 2003 totaling \$4.0 million. The Company's obligation to the lender is secured by a first priority lien on substantially all of the Company's assets and bears interest at a rate equal to the prime rate (4.25% at January 3, 2003) plus an applicable interest margin from 1% to 5% which is based on the Company's ratio of funded debt to earnings before interest, taxes, depreciation, and amortization (EBITDA) at each fiscal quarter on a trailing 12-month basis. In addition, the Company is required to pay a commitment fee of .25% to 1.25% of the unused amount of

Edgar Filing: STAAR SURGICAL COMPANY - Form 10-K/A

the line of credit also based on a ratio of funded debt to EBITDA. Since the Company reported losses throughout 2002, it was charged the maximum total interest rate allowed under the agreement of prime plus a 5% margin (9.25%) and the maximum commitment fee of 1.25% at January 3, 2003.

The agreement also requires the Company to satisfy certain financial tests, which include positive and negative covenants such as the maintenance of certain levels of liquidity, operating cash flows, tangible net worth, and operating income. As of January 3, 2003, the Company was not in compliance with the tangible net worth covenants of the agreement. The Company has obtained a waiver from the lender who agreed to waive the events of default resulting from the covenant violations. Borrowings outstanding under the note as of January 3, 2003 and December 28, 2001, were approximately \$2.8 million and \$5.7 million, respectively. As of January 3, 2003 and December 28, 2001, the note provided for borrowings of up to \$3.7 million and \$7.0 million, respectively.

On March 26, 2003, the Company and its domestic lender executed an agreement to extend the maturity date of the Company's \$3.0 million line-of-credit for one year to March 31, 2004. The line-of-credit bears interest at a rate equal to the prime rate (4.25% at January 3, 2003) plus an interest margin of 5%. In addition, the Company is required to pay a commitment fee of 1.25% per annum of the unused amount of the line-of-credit. All other terms and conditions are generally unchanged except that the cash flow and operating income covenants of the agreement do not commence until the third quarter of 2003 and minimum tangible net worth covenants were reduced.

STAAR SURGICAL COMPANY AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

A subsidiary of the Company has a revolving credit facility with a Swiss bank, which as amended in fiscal 2001, provides for borrowings of up to 4.5 million Swiss Francs CHF (\$3.2 million based on the exchange rate on January 3, 2003). The credit facility is divided into two parts: Part A provides for borrowings of up to CHF 3.0 million (\$2.1 million based on the exchange rate on January 3, 2003) and does not have a termination date; Part B provides for borrowings of up to CHF 1.5 million (\$1.1 million based on the exchange rate on January 3, 2003). The loan amount under Part B of the agreement reduces by CHF 250,000 (\$178,000 based on the exchange rate on January 3, 2003) semi-annually beginning June 30, 2002. The credit facility is secured by a general assignment of claims.

The loan agreement provides for borrowings on a current or fixed-term basis. The interest rate on current advances is 6.5% per annum at January 3, 2003 plus a commission rate of 0.25%, payable each quarter. The base interest rate for fixed-term advances follows Euromarket conditions for loans of a corresponding term and currency plus an individual margin. The fixed-term rate at January 3, 2003 was 4.6%. Borrowings outstanding under the current account as of January 3, 2003 were CHF 90,000 (\$64,000 based on the exchange rate on January 3, 2003). Fixed term advances at January 3, 2003 were CHF 4.1 million (\$2.9 million based on the exchange rate on January 3, 2003).

A subsidiary of the Company has a revolving credit facility with a German bank that provides for borrowings of up to approximately 200,000 EUR (\$207,000 at the exchange rate on January 3, 2003) at an interest rate of 8.5%. The loan, originally due February 28, 2003, was extended on October 8, 2002 to August 31, 2003. Payments in the amount of 50,000 EUR (\$52,000 at the exchange rate on January 3, 2003) were due monthly beginning December 31, 2001. The amended agreement reduced the monthly payment to 25,000 EUR (\$26,000 at the exchange rate on January 3, 2003). The bank also agreed to waive the September 2002 and October 2002 payments. There were no other changes to the original terms of the agreement. The loan is secured by an assignment of accounts receivable and inventory. There were no borrowings outstanding as of January 3, 2003.

The subsidiary negotiated another credit facility with a different German bank to replace the one that expires on August 31, 2003. The new agreement, effective January 13, 2003, provides for borrowings of up to 210,000 EUR (\$199,000 at the exchange rate on the date of the agreement) at an interest rate of 8.5%. The note is due November 30, 2003 and is personally guaranteed by the subsidiary's president. The agreement includes a covenant which prevents the subsidiary from paying dividends.

NOTE 6 INCOME TAXES

Income tax provision (benefit) (in thousands)

| | 2002 | 2001 | 2000 |
|--------------|-----------------|-----------------|-----------------|
| | <u>Restated</u> | <u>Restated</u> | <u>Restated</u> |
| Current | | | |
| U.S. federal | \$ (995) | \$ 484 | \$ (393) |
| State | (74) | 146 | 18 |

Edgar Filing: STAAR SURGICAL COMPANY - Form 10-K/A

| | | | |
|--------------------------------|-----------------|-------------------|-------------------|
| Foreign | 742 | 258 | 317 |
| | <u>(327)</u> | <u>888</u> | <u>(58)</u> |
| Deferred | | | |
| U.S. federal and state | 9,021 | (4,537) | (6,700) |
| Foreign | 111 | | |
| | <u>9,132</u> | <u>(4,537)</u> | <u>(6,700)</u> |
| Income tax provision (benefit) | <u>\$ 8,805</u> | <u>\$ (3,649)</u> | <u>\$ (6,758)</u> |

F-15

STAAR SURGICAL COMPANY AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Included in the fiscal year 2000 current United States federal net tax benefit is the carryback of a portion of 2000 net taxable loss to 1998. This carryback resulted in a refund of \$839,000 of taxes previously paid. Legislation enacted on March 9, 2002 (HR 3090) enabled the Company to carryback a portion of the federal 2001 net operating loss to 1996, 1997 and 1998. Since this legislation was not enacted as of the end of fiscal year 2001, the benefit of \$959,000 from this carryback was recorded in 2002. Total federal net operating loss carryforward as of January 3, 2003 is \$36.7 million expiring between 2020 and 2022.

The Company has net income taxes payable at January 3, 2003 and December 28, 2001 of \$171,000 and \$239,000, respectively, \$440,000 and \$0 is classified as prepaids, deposits and other current assets and \$611,000 and \$239,000, primarily related to foreign income taxes, is classified as other current liabilities.

The provision (benefit) for income taxes is different from that which would be obtained by applying the statutory Federal income tax rate to loss before income taxes. The items causing this difference are as follows (in thousands):

| | 2002 | | 2001 | | 2000 | |
|--|------------|----------|------------|--------|------------|-------|
| | Restated | | Restated | | Restated | |
| Computed tax provision (benefit) on losses at statutory rate | \$ (2,685) | 34.0 % | \$ (6,293) | 34.0% | \$ (8,793) | 34.0% |
| Increase (decrease) in taxes resulting from: | | | | | | |
| Permanent differences | 38 | (0.5) | 39 | (0.2) | 73 | (0.3) |
| State taxes, net of federal income tax benefit | 1,305 | (16.5) | (763) | 4.1 | (621) | 2.4 |
| Tax effect attributed to foreign operations | (1,245) | 15.8 | (345) | 1.9 | 505 | (2.0) |
| Loss related to previously excluded foreign earnings | | | | | 706 | (2.7) |
| Valuation allowance | 11,392 | (144.3) | 3,713 | (20.1) | 1,372 | (5.3) |
| Effective tax provision (benefit) and rate | \$ 8,805 | (111.5)% | \$ (3,649) | 19.7% | \$ (6,758) | 26.1% |

Undistributed earnings of the Company's foreign subsidiaries amounted to approximately \$9.7 million at January 3, 2003. Undistributed earnings are considered to be indefinitely reinvested and, accordingly, no provision for United States federal and state income taxes has been provided thereon.

Upon distribution of earnings in the form of dividends or otherwise, the Company would be subject to both United States income taxes (subject to an adjustment for foreign tax credits) and withholding taxes payable to the various foreign countries. Determination of the amount of unrecognized deferred United States income tax liability is not practicable because of the complexities associated with its hypothetical calculation.

STAAR SURGICAL COMPANY AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of the Company's deferred tax assets (liabilities) as of January 3, 2003 and December 28, 2001 are as follows (in thousands):

| | 2002 | 2001 |
|---|----------------------|-------------------|
| | <u>Restated</u> | <u>Restated</u> |
| Current deferred tax assets (liabilities): | | |
| Allowance for doubtful accounts | \$ 131 | \$ 174 |
| Inventory reserves and uniform capitalization | 576 | 2,478 |
| Accrued vacation | 153 | 177 |
| State taxes | 3 | 14 |
| Deferred revenue | 33 | 87 |
| Reserve for restructuring costs | | 2,387 |
| Other accruals | | (13) |
| Valuation allowance | (896) | |
| | <u> </u> | <u> </u> |
| Total current deferred tax assets (liabilities) | \$ <u> </u> | \$ <u>5,304</u> |
| Non-current deferred tax assets (liabilities): | | |
| Net operating loss and capital loss carryforwards | \$ 14,804 | \$ 5,871 |
| Business, foreign and AMT credit carryforwards | 1,132 | 885 |
| Depreciation and amortization | (781) | (447) |
| Reserve for notes receivable | 744 | 1,405 |
| Reserve for restructuring costs | 1,573 | 402 |
| Subpart F income | 103 | |
| Capitalized R&D | 136 | |
| Valuation allowance | (17,711) | (4,288) |
| | <u> </u> | <u> </u> |
| Total non-current deferred tax assets (liabilities) | \$ <u> </u> | \$ <u>3,828</u> |

SFAS No. 109, Accounting for Income Taxes, (SFAS 109) requires that a valuation allowance be established when it is more likely than not that all or a portion of a deferred tax asset may not be realized. Cumulative losses weigh heavily in the assessment of the need for a valuation allowance. In 2002, due to the Company's recent history of losses, an increase to the valuation allowance was recorded as a non-cash charge to tax expense in the amount of \$9.0 million. As a result, the valuation allowance fully offsets the value of deferred tax assets on the Company's balance sheet as of January 3, 2003.

NOTE 7 BUSINESS ACQUISITIONS

Edgar Filing: STAAR SURGICAL COMPANY - Form 10-K/A

During the year ended January 3, 2003, the Company acquired the remaining 20% interest in its German subsidiary at its book value of \$426,000, from the subsidiary's president in exchange for cancellation of amounts due from the subsidiary's president of \$955,000 less bonuses due to the subsidiary's president of \$87,000, resulting in goodwill of \$442,000. The terms of the agreement also provided for the cancellation of 75,000 unexercised stock options previously issued to the subsidiary's president and an agreement not to compete with the Company for a period of ten years. For the year ended January 3, 2003, the Company reflected the activity as a wholly owned subsidiary, whereas for the years ended December 28, 2001 and December 29, 2000, the 20% interest that was not owned was reflected as a minority interest on the consolidated statement of operations.

F-17

STAAR SURGICAL COMPANY AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Pro forma amounts for the acquisition are not included, as the effect on operations is not material to the Company's consolidated financial statements.

NOTE 8 STOCKHOLDERS' EQUITY

Common Stock

In fiscal year 2000, the Company issued 143,000 shares to consultants for services rendered to the Company. Also, during 2000, the Company completed a private placement with institutional investors of 1.5 million shares of the Company's common stock, for net proceeds of \$18.7 million.

In fiscal year 2001, the Company issued 192,000 shares to consultants for services rendered to the Company.

During fiscal year 2002, the Company issued 39,000 shares to consultants for services rendered to the Company and 3,000 shares to an employee relating to an employment contract. Also during 2002, the Company acquired 243,000 shares of treasury stock from a former officer in settlement of notes receivable (See Note 17).

Receivables from Officers and Directors

As of January 3, 2003 and December 28, 2001, notes receivable from former officers and directors totaling \$5.5 million and \$7.5 million, respectively, were outstanding. The notes were issued in connection with purchases of the Company's common stock and bear interest at rates ranging between 3.69% and 9.75% per annum, or at the lowest federal applicable rate allowed by the Internal Revenue Service. The notes are secured by stock pledge agreements and mature on various dates through June 1, 2006.

As of January 3, 2003 and December 28, 2001 reserves against notes receivable from officers and directors were \$1.8 million and \$3.6 million, respectively.

During fiscal year 2002, the Company and its former Chief Executive Officer, John R. Wolf, dismissed all legal actions between them pursuant to a settlement agreement dated November 12, 2002. The agreement provided for completion of Mr. Wolf's transfer of 243,000 shares of Company stock pursuant to the Form 4 executed May 9, 2000, in satisfaction of \$2.1 million in promissory notes executed by Mr. Wolf in favor of the Company.

Also during the year ended January 3, 2003, the Company entered into a promissory note in the amount of \$560,000 pursuant to the terms of a settlement agreement with a law firm, of which a principal was a former officer, director and stockholder of the Company. Terms of the note, secured by trade accounts receivable of the law firm, include interest at the rate of 5% with monthly payment of principal and interest due beginning July 1, 2002 through June 1, 2006. During the year ended January 3, 2003 payments against the note were received in the amount of \$80,000.

The Company entered into a second promissory note in the amount of \$2.2 million, pursuant to the terms of the same settlement agreement, with the former officer's widow. Terms of the note, secured by a stock pledge agreement, includes interest at the rate of 5% with principal and interest due on or before March 29, 2006. The note also provides for escalation in the interest rate to 9.75% if the bid price of the Company's common stock trades at \$8.00 or greater on any public stock exchange for a period of 20 consecutive trading days, or if the stock permanently ceases to trade on any public stock exchange. Additionally, the note provides an acceleration of payment in the event the closing bid price of the common stock of the Company trades at \$10.00 or greater on any public stock exchange for a period of 20 consecutive trading days.

STAAR SURGICAL COMPANY AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Options

The table below summarizes the transactions in the Company's stock option plans (in thousands except per share data):

| | Number of Shares | Weighted Average Exercise Price |
|---|---------------------|--|
| Balance at December 31, 1999 | 1,460 | \$ 7.75 |
| Options granted | 1,604 | \$ 10.35 |
| Options exercised | (498) | \$ 7.03 |
| Options forfeited / cancelled | (674) | \$ 8.05 |
| Balance at December 29, 2000 | 1,892 | \$ 9.95 |
| Options granted | 1,114 | \$ 6.98 |
| Options exercised | (18) | \$ 3.57 |
| Options forfeited / cancelled | (77) | \$ 9.77 |
| Balance at December 28, 2001 | 2,911 | \$ 8.85 |
| Options granted | 972 | \$ 3.73 |
| Options exercised | - | \$ - |
| Options forfeited / cancelled | (745) | \$ 10.55 |
| Balance at January 3, 2003 | 3,138 | \$ 6.86 |
| Options exercisable (vested) at January 3, 2003 | 2,405 | \$ 7.43 |

Under provisions of the Company's 1991 Stock Option Plan, 2.0 million shares were reserved for issuance. Generally, options under this plan are granted at fair market value at the date of the grant, become exercisable over a 3-year period, or as determined by the Board of Directors, and expire over periods not exceeding 10 years from the date of grant. At January 3, 2003, December 28, 2001, and December 29, 2000 options for 379,000, 384,000 and 434,000 shares were outstanding, with exercise prices ranging between \$2.50 to \$14.50 per share.

In fiscal year 1995, the Company adopted the 1995 Consultant Stock Plan, authorizing the granting of options to purchase or awards of the Company's common stock. Generally, options under the plan are granted at fair market value at the date of the grant, become exercisable on the date of grant and expire 10 years from the date of grant. Pursuant to this plan, options for 545,000, 472,000 and 279,000 were outstanding at January 3, 2003, December 28, 2001, and December 29, 2000, respectively.

Edgar Filing: STAAR SURGICAL COMPANY - Form 10-K/A

In fiscal year 1996, the Board of Directors approved the 1996 Non-Qualified Stock Plan, authorizing the granting of options to purchase or awards of the Company's common stock. Under provisions of the Non-Qualified Stock Plan, 600,000 shares were reserved for issuance. Generally, options under the plan are granted at fair market value at the date of the grant, become exercisable over a 3-year period, or as determined by the Board of Directors, and expire over periods not exceeding 10 years from the date of grant. Pursuant to this plan, options for 170,000, 170,000 and 175,000 shares were outstanding at January 3, 2003, December 28, 2001 and December 29, 2000, respectively. The options were originally issued with an exercise price of \$12.50 per share. During fiscal year 1998 the exercise price was reduced to \$6.25 per share by action of the Board of Directors.

In fiscal year 1998, the Board of Directors approved the 1998 Stock Option Plan, authorizing the granting of incentive options and/or non-qualified options to purchase or awards of the Company's common stock. Under the

STAAR SURGICAL COMPANY AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

provisions of the plan, 1.0 million shares were reserved for issuance; however, the maximum number of shares authorized may be increased provided such action is in compliance with Article IV of the Plan. During fiscal year 2001, pursuant to Article IV of the Plan, the stockholders of the Company authorized an additional 1.5 million shares. Generally, options under the plan are granted at fair market value at the date of the grant, become exercisable over a 3-year period, or as determined by the Board of Directors, and expire over periods not exceeding 10 years from the date of grant. Pursuant to the plan, options for 1.5 million, 1.4 million and 810,000 shares were outstanding at January 3, 2003, December 28, 2001 and December 29, 2000, respectively, with exercise prices ranging between \$2.00 and \$15.75 per share.

In fiscal year 2001, the Board of Directors approved the Stock Option Plan and Agreement for the Company's Chief Executive Officer authorizing the granting of options to purchase or awards of the Company's common stock. Generally, options under the plan are granted at fair market value at the date of grant, become exercisable over a 3-year period, or as determined by the Board of Directors, and expire 10 years from the date of grant. Pursuant to this plan, options for 500,000 were outstanding at January 3, 2003, December 28, 2001, and December 29, 2000, respectively, with an exercise price of \$11.125.

In fiscal year 2000, officers, employees and others exercised 498,000 options from the 1990, 1991, 1996, 1998 and non-qualified stock option plans at prices ranging from \$2.50 to \$13.63 resulting in cash and note proceeds totaling \$3.5 million.

In fiscal year 2001, officers, employees and others exercised 18,000 options from the 1991 and 1996 stock option plans at prices ranging from \$2.50 to \$6.25 resulting in cash proceeds totaling \$62,000.

In fiscal year 2002, no options from any of the Company's stock option plans were exercised.

SFAS No. 123, Accounting for Stock-Based Compensation requires the Company to provide pro forma information regarding net income and earnings per share as if compensation expense for the Company's stock option plans had been determined in accordance with the fair value based method. The fair value of each stock option grant is estimated on the grant date using the Black-Scholes option-pricing model with the following assumptions:

| | <u>2002</u> | <u>2001</u> | <u>2000</u> |
|------------------------------------|-------------|-------------|-------------|
| Dividend yield | 0% | 0% | 0% |
| Expected volatility | 66% | 64% | 42% |
| Risk-free interest rate | 4.50% | 4.50% | 4.50% |
| Expected holding period (in years) | 1 to 3 | 1 to 3 | 1 to 5 |

The weighted average fair value of options granted during the year ended January 3, 2003, December 28, 2001 and December 29, 2000, were \$1.27 to \$2.44, \$0.55 to \$3.72 and \$1.32 to \$4.55, respectively.

STAAR SURGICAL COMPANY AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Pro forma net loss and loss per share for fiscal year 2002, 2001 and 2000 had the Company accounted for stock options issued to employees and others in accordance with the fair value method of SFAS 123 are as follows (in thousands, except per share data):

| | 2002 | 2001 | 2000 |
|---|--------------------|--------------------|--------------------|
| | <u>Restated</u> | <u>Restated</u> | <u>Restated</u> |
| Net loss | | | |
| As reported | \$ (16,778) | \$ (15,000) | \$ (19,192) |
| Add: | | | |
| Stock-based employee compensation expense included in reported net loss, net of related tax effects | | | |
| Deduct: | | | |
| Total stock-based employee compensation expense determined under fair value based method for all awards, net of related tax effects | (1,679) | (1,488) | (1,597) |
| Pro forma | <u>\$ (18,457)</u> | <u>\$ (16,488)</u> | <u>\$ (20,789)</u> |
| Basic and diluted loss per share | | | |
| As reported | \$ (0.98) | \$ (0.88) | \$ (1.25) |
| Pro forma | \$ (1.08) | \$ (0.97) | \$ (1.35) |

Due to the fact that the Company's stock option programs vest over many years and additional awards are made each year, the above pro forma numbers are not indicative of the financial impact had the disclosure provisions of SFAS 123 been applicable to all years of previous option grants. The above numbers do not include the effect of options granted prior to 1995 that vested in 1996 through 2002.

The following table summarizes information about stock options outstanding and exercisable at January 3, 2003 (in thousands, except per share data):

| Range of Exercise Prices | Options | | | | |
|-----------------------------|---|---|--|--|------------------------------------|
| | Outstanding | | | Exercisable | |
| | Number Outstanding at 1/03/03 (in thousands) | Weighted- Average Remaining Contractual Life | Weighted- Average Exercise Price | Number Exercisable at 01/03/03 (in thousands) | Weighted-Average Exercise Price |
| \$1.70 to \$2.50 | 259 | 4.3 years | \$ 1.97 | 213 | \$ 1.94 |

Edgar Filing: STAAR SURGICAL COMPANY - Form 10-K/A

| | | | | | |
|--------------------|--------------|------------------|----------------|--------------|----------------|
| \$2.82 to \$4.12 | 956 | 4.8 years | \$ 3.44 | 544 | \$ 3.39 |
| \$4.45 to \$6.60 | 643 | 3.1 years | \$ 5.67 | 497 | \$ 5.93 |
| \$7.50 to \$11.25 | 1,110 | 6.0 years | \$10.61 | 1,009 | \$10.64 |
| \$11.38 to \$15.75 | 170 | 7.3 years | \$13.63 | 142 | \$13.63 |
| | <u>3,138</u> | <u>5.0 years</u> | <u>\$ 6.86</u> | <u>2,405</u> | <u>\$ 7.43</u> |

Warrants

The table below summarizes the transactions related to warrants to purchase the Company's common stock:

| | Number of Shares | Weighted Average Exercise Price |
|--|-----------------------------|--|
| Balance at December 28, 2001 and December 29, 2000 | 5,000 | \$ 1.20 |
| Warrants exercised | (5,000) | \$ 1.20 |
| Balance at January 3, 2003 | <u>0</u> | <u>\$ 0</u> |

STAAR SURGICAL COMPANY AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**NOTE 9 COMMITMENTS AND CONTINGENCIES****Lease Obligations**

The Company leases certain property, plant and equipment under capital and operating lease agreements.

Annual future minimum lease payments under non-cancelable operating lease commitments as of January 3, 2003 are as follows (in thousands):

| <u>Fiscal Year</u> | |
|--------------------|---------|
| 2003 | \$ 713 |
| 2004 | 348 |
| 2005 | 299 |
| 2006 | 232 |
| 2007 | 55 |
| | <hr/> |
| Total | \$1,647 |
| | <hr/> |

Rent expense was approximately \$1.1 million for each of the years ended January 3, 2003, December 28, 2001 and December 29, 2000, respectively.

Supply Agreement

In May 1999, the Company entered into a license and supply agreement with another manufacturer to license and re-sell one of the manufacturer's products. Under the terms of the agreement, the Company was committed to purchase the specified product for a total sum of \$3.2 million over 18 months. In September 2001, the supply agreement was amended reducing the minimum contractual amount that the Company is obligated to purchase from the manufacturer to \$2.5 million over a 24 month period commencing September 1, 2001. The agreement, as amended, can be cancelled at the end of the 24 month period by either party upon four months written notice. Purchases under the agreement for fiscal 2002 and 2001 were approximately \$1.3 million and \$735,000, respectively.

In December 2000, the Company entered into a minimum purchase agreement with another manufacturer for the purchase of viscoelastic solution. In addition to the minimum purchase requirement, the Company is also obligated to pay an annual regulatory maintenance fee. The agreement contains provisions to increase the minimum annual purchases in the event that the Seller gains regulatory approval of the product in

Edgar Filing: STAAR SURGICAL COMPANY - Form 10-K/A

other markets, as requested by the Company. Purchases under the agreement for fiscal 2002 and 2001 were approximately \$383,000 and \$184,000, respectively.

As of January 3, 2003 estimated annual purchase commitments under these contracts are as follows (in thousands):

| Fiscal Year | |
|--------------------|----------------|
| 2003 | \$1,065 |
| 2004 | 600 |
| 2005 | 600 |
| 2006 | 600 |
| Total | \$2,865 |

F-22

STAAR SURGICAL COMPANY AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Litigation and Claims

The Company is party to various claims and legal proceedings arising out of the normal course of its business. These claims and legal proceedings relate to contractual rights and obligations, employment matters, stockholder suits and claims of product liability. While there can be no assurance that an adverse determination of any such matters could not have a material adverse impact in any future period, management does not believe, based upon information known to it, that the final resolution of any of these matters will have a material adverse effect upon the Company's consolidated financial position and annual results of operations and cash flows.

NOTE 10 OTHER LIABILITIES

Other Current Liabilities

Included in other current liabilities at January 3, 2003 and December 28, 2001 are approximately \$1.3 million and \$1.4 million of commissions due to outside sales representatives and accrued salaries and wages of \$805,000 and \$940,000, respectively.

NOTE 11 RELATED PARTY TRANSACTIONS

The Company has had significant related party transactions as discussed in Notes 4, 7 and 8.

The Company issues options to purchase 60,000 shares of its common stock at fair market value on the date of grant to members of its Board of Directors upon election or reelection for services provided as Board members.

In addition to notes secured by stock pledge agreements (see Note 8), the Company holds other various promissory notes from current and former officers and directors of the Company. The notes, which provide for interest at the lowest applicable rate allowed by the Internal Revenue Code, are due on demand. Amounts due from officers and directors and included in prepaids, deposits, and other current assets at January 3, 2003 and December 28, 2001 were \$158,000 and \$460,000, respectively.

In March 2001, the Company entered into a consulting agreement with one of the members of its Board of Directors. In exchange for services, the Company issued an option to purchase 20,000 shares of the Company's common stock at fair market value on the date of grant, in addition to a monthly retainer of \$6,000, and a per-diem rate after six days worked of \$1,000. Amounts paid under the agreement during the year ended January 3, 2003 and December 28, 2001 were \$73,000 and \$93,000, respectively.

The Company had a consulting contract with a corporation owned by an employee of one of its foreign subsidiaries. The consulting contract, which began October 1, 1999 and ending October 1, 2005, provided for monthly payments of \$20,000 in exchange for specified services. During fiscal year 2001, the parties agreed to terminate the contract at a discount in exchange for cash and forgiveness of a note receivable due the subsidiary from the employee. Debt forgiveness totaled \$658,000 (1.4 million DM at the exchange rate in effect on the settlement date). During fiscal year 2002, 2001, and 2000, amounts paid or accrued under the contract totaled \$0, \$180,000, and \$240,000, respectively. During the year ended January 3, 2003, a pension obligation in the amount of \$257,000, which was included in other long-term liabilities at December 28, 2001, was paid to the employee. Amounts due from the employee and included in prepaids, deposits, and other current assets at December 28, 2001 were \$523,000 (1.2 million DM at the exchange rate on December 28, 2001). Additional amounts due were cancelled during the year ended January 3, 2003 in exchange for the purchase of the remaining 20% interest of the subsidiary (see Note 7).

STAAR SURGICAL COMPANY AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

During fiscal year 2001 and 2000, a law firm, of which a principal was an officer, director and stockholder of the Company, received approximately \$1.5 million and \$2.0 million, respectively, for fees in connection with legal services performed on behalf of the Company.

NOTE 12 SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION

Interest paid was \$580,000, \$640,000 and \$1.5 million for the years ended January 3, 2003, December 28, 2001 and December 29, 2000, respectively. Income taxes paid amounted to approximately \$719,000, \$479,000 and \$648,000 for the years ended January 3, 2003, December 28, 2001 and December 29, 2000, respectively.

| | <u>2002</u> | <u>2001</u> | <u>2000</u> |
|---|-------------|-------------|-------------|
| Non cash financing activities: | | | |
| Notes receivable from officers and directors (Note 8) | \$ (2,128) | \$ | \$ 1,167 |
| Notes receivable reserve | 1,814 | | |
| Prepays, deposits and other current assets | (658) | | |
| Treasury stock acquired | 972 | | |
| Acquisition of business: | | | |
| Minority interest acquired | \$ 426 | \$ | \$ |
| Goodwill | 442 | | |
| Cancellation of amounts receivable | (868) | | |

NOTE 13 OTHER CHARGES

On June 22, 2000, the Company announced the details of its plan of restructuring. In conjunction with the implementation of the plan, the Company recorded a pretax charge to earnings of approximately \$13.8 million in the second quarter of fiscal year 2000. The charges include approximately \$900,000 for restructuring of certain subsidiaries, approximately \$4.0 million to write-off patents that were determined to have no future value to the Company, approximately \$1.9 million of costs incurred by the Company relating to activities that were abandoned, approximately \$4.1 million relating to severance and other employee separation costs, approximately \$1.9 million relating to the disposition of investment and assets related to the Company's abandoned entry into the Lasik market, and approximately \$1.0 million relating to the closure of a foreign subsidiary. As part of the restructuring plan, a total of 19 employees were laid-off, terminated or resigned.

In addition, the Company wrote-off approximately \$5.2 million in inventory that no longer fit the Company's future direction and recorded an approximate \$4.7 million charge related to the write-off of its Japanese joint venture. At December 28, 2001, the Company had approximately \$100,000 of accrued restructuring charges consisting of future payments to former employees and lease obligations.

Edgar Filing: STAAR SURGICAL COMPANY - Form 10-K/A

In June 2001 management completed an extensive operational review of the Company. Based upon that review, in August 2001 the Company implemented a plan that management believes will allow the Company to become profitable. As a result of implementing the plan, the Company significantly changed its manufacturing processes and location including consolidating lathing activity into the Swiss manufacturing site from the current dual site operations and reducing molded lens capacity at the California site. The Company also reduced its workforce and closed certain overseas operations. In conjunction with the implementation of the plan, the Company recorded pretax charges of approximately \$7.8 million in the third and fourth quarters of fiscal year 2001. Planned charges include approximately \$3.7 million in fixed asset write-offs, \$300,000 in severance and employee relocation costs, and \$1.0 million for subsidiary closures. Additionally, the Company reserved \$2.1 million of notes receivable from former officers and directors of the Company and paid \$700,000 in consideration for the early termination of a consulting contract with the president of the Company's German subsidiary.

F-24

STAAR SURGICAL COMPANY AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The Company also wrote off \$6.4 million of inventory related to voluntary product recalls and excess and obsolete inventory in the second and fourth quarters of 2001. The amount is included in cost of sales at December 28, 2001.

In connection with its business strategy to reduce operating expenses, announced during the third quarter of 2001, the Company completed the sale of its South African subsidiary and closure of its Swedish and Canadian subsidiaries during the year ended January 3, 2003. As a result of these transactions the Company recorded \$1.2 million of subsidiary closure charges. The charges were primarily related to the recognition of deferred losses resulting from the translation of foreign currency statements into U.S. dollars (previously included in equity in the balance sheet in accordance with SFAS No. 52). Since the charges had been included in equity their subsequent recognition, while impacting retained earnings, had no impact on total stockholders' equity. The Company will continue its presence in the South African and Swedish markets by selling through distributors and in the Canadian market by selling through independent sales representatives.

Also included in other charges at January 3, 2003 is \$230,000 in employee separation costs.

NOTE 14 NET LOSS PER SHARE

The following is a reconciliation of the weighted average number of shares used to compute basic and diluted loss per share (in thousands):

| | <u>2002</u> | <u>2001</u> | <u>2000</u> |
|--|---------------|---------------|---------------|
| Basic weighted average shares outstanding | 17,142 | 17,003 | 15,378 |
| Diluted effect of stock options and warrants | | | |
| Diluted weighted average shares outstanding | <u>17,142</u> | <u>17,003</u> | <u>15,378</u> |

NOTE 15 GEOGRAPHIC AND PRODUCT DATA

The Company develops, manufactures and distributes medical devices used in minimally invasive ophthalmic surgery. Substantially all of the Company's revenues result from the sale of the Company's medical devices. The Company distributes its medical devices in the cataract, refractive and glaucoma segments within ophthalmology. During the years presented, revenues from the refractive and glaucoma segments were 5% or less of total revenue. Accordingly, the difference is not significant enough for the Company to account for these products separately or to justify segmented reporting by product type.

Edgar Filing: STAAR SURGICAL COMPANY - Form 10-K/A

The Company markets and sells its products in over 39 countries and has manufacturing sites in the United States and Switzerland. Other than the United States and Germany, the Company does not conduct business in any country in which its sales in that country exceed 5% of consolidated sales. Sales are attributed to countries based on location of customers. The composition of the Company's sales to unaffiliated customers between those in the United States, Germany, and those in other locations for each year, is set forth below (in thousands).

| | <u>2002</u> | <u>2001</u> | <u>2000</u> |
|--|-------------------|-------------------|-------------------|
| Sales to unaffiliated customers | | | |
| U.S. | \$ 24,082 | \$ 27,465 | \$ 29,501 |
| Germany | 16,081 | 14,907 | 14,182 |
| Other | 7,717 | 7,865 | 10,303 |
| | <u> </u> | <u> </u> | <u> </u> |
| Total | \$ 47,880 | \$ 50,237 | \$ 53,986 |
| | <u> </u> | <u> </u> | <u> </u> |

STAAR SURGICAL COMPANY AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The composition of the Company's property, plant and equipment between those in the United States, Switzerland, and those in other countries is set forth below (in thousands).

| | <u>2002</u> | <u>2001</u> |
|--------------------------------------|-------------------|-------------------|
| Property, Plant and Equipment | | |
| U.S. | \$ 5,221 | \$ 6,316 |
| Switzerland | 1,844 | 2,123 |
| Other | 373 | 303 |
| | <u> </u> | <u> </u> |
| Total | \$ 7,438 | \$ 8,742 |
| | <u> </u> | <u> </u> |

The Company sells its products internationally, which subjects the Company to several potential risks, including fluctuating exchange rates (to the extent the Company's transactions are not in U.S. dollars), regulation of fund transfers by foreign governments, United States and foreign export and import duties and tariffs and political instability.

NOTE 16 QUARTERLY FINANCIAL DATA (UNAUDITED)

Summary unaudited quarterly financial data from continuing operations for fiscal 2002 and 2001 is as follows (in thousands except per share data):

| | 1st Qtr. | 2nd Qtr. | 3rd Qtr. | 4th Qtr. |
|----------------------------------|-------------------|-------------------|-------------------|-------------------|
| January 3, 2003 | Restated | Restated | Restated | Restated |
| | <u> </u> | <u> </u> | <u> </u> | <u> </u> |
| Revenues | \$ 11,731 | \$ 12,088 | \$ 11,201 | \$ 13,228 |
| Gross profit | 5,712 | 6,024 | 5,620 | 6,793 |
| Net loss | (962) | (3,844) | (2,073) | (9,899) |
| Basic and diluted loss per share | (.06) | (.22) | (.12) | (.58) |
| | <u> </u> | <u> </u> | <u> </u> | <u> </u> |
| December 28, 2001 | Restated | Restated | Restated | Restated |
| | <u> </u> | <u> </u> | <u> </u> | <u> </u> |
| Revenues | \$ 13,001 | \$ 12,890 | \$ 12,154 | \$ 12,741 |
| Gross profit | 7,822 | 1,865 | 6,688 | 6,208 |
| Net loss | (185) | (4,133) | (1,946) | (8,736) |
| Basic and diluted loss per share | (.01) | (.24) | (.11) | (.51) |

Edgar Filing: STAAR SURGICAL COMPANY - Form 10-K/A

Quarterly and year-to-date computations of loss per share amounts are made independently. Therefore, the sum of the per share amounts for the quarters may not agree with the per share amounts for the year.

NOTE 17 FOURTH QUARTER SIGNIFICANT ITEMS

On November 12, 2002, the Company and its former Chief Executive Officer, John R. Wolf, settled all legal actions between them (see Note 8).

During the quarter ended January 3, 2003, the Company acquired the remaining 20% interest of its German subsidiary from the subsidiary's president (see Note 7).

During the quarter ended January 3, 2003, the Company recorded a \$9.0 million increase in its deferred tax asset valuation allowance (see Note 6).

F-26

STAAR SURGICAL COMPANY AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

NOTE 18 SUBSEQUENT EVENTS

The Company negotiated a credit facility with a German bank to replace the credit facility that expires on August 31, 2003. The new credit facility, effective January 13th, 2003, provides for borrowings of up to \$210,000 EUR (\$199,000 at the exchange rate on the date of the agreement) at an interest rate of 8.5%. The note is due on November 30, 2003 and is personally guaranteed by the subsidiary's president. The agreement includes a covenant which prevents the subsidiary from paying dividends.

On February 27, 2003, the Company and Richard Leza, former Vice President of Finance, Business Development and Corporate Strategy, settled their disputes. Pursuant to the settlement, the Company agreed to pay Mr. Leza monthly payments totaling \$180,000 over a 15-month period. The Company also agreed to issue Mr. Leza an option to purchase 75,000 shares of the Company's common stock and forgave a note receivable of \$120,000.

On March 26, 2003, the Company and its domestic lender executed an agreement to extend the maturity date of the Company's \$3.0 million line-of-credit from one year to March 31, 2004. The line-of-credit bears interest at a rate equal to the prime rate (4.25% at January 3, 2003) plus an interest margin of 5%. In addition, the Company is required to pay a commitment fee of 1.25% per annum of the unused amount of the line-of-credit. All other terms and conditions are generally unchanged except that the cash flow and operating income covenants of the agreement do not commence until the third quarter of 2003 and minimum tangible net worth covenants were reduced.

NOTE 19 PRIOR-PERIOD ADJUSTMENTS

The Company has restated its previously issued consolidated financial statements for the years ended January 3, 2003, December 28, 2001 and December 29, 2000 to report interest income on notes receivable from officers and directors on an accrual basis consistent with accounting principles generally accepted in the United States of America. The impact of the restatement on interest income and loss per share for the periods is as follows (in thousands):

| | Year Ended January 3, 2003 | | | Year Ended December 28, 2001 | | | Year Ended December 29, 2000 | | |
|-----------------------------|-------------------------------|--------------|-----------|---------------------------------|--------------|-----------|---------------------------------|--------------|-----------|
| | Previously Reported | Inc (Dec) | Restated | Previously Reported | Inc (Dec) | Restated | Previously Reported | Inc (Dec) | Restated |
| Interest income | \$ 135 | \$ 226 | \$ 361 | \$ 270 | \$ (269) | \$ 1 | \$ 1,294 | \$ (468) | \$ 826 |
| Interest income, net of tax | | | | \$ 167 | \$ (167) | | \$ 802 | \$ (290) | \$ 512 |
| Loss per share | \$ (1.00) | \$.02 | \$ (0.98) | \$ (0.87) | \$ (0.01) | \$ (0.88) | \$ (1.23) | \$ (.02) | \$ (1.25) |

Edgar Filing: STAAR SURGICAL COMPANY - Form 10-K/A

There is no income tax effect of the restatement on earnings for the 2002 fiscal year since the Company reported losses and did not record income tax benefits thereon.

The impact of the restatement on the consolidated balance sheet is as follows (in thousands):

| | As Previously | | As Previously | |
|--|------------------------|------------------------|--------------------------|--------------------------|
| | Reported | As Revised | Reported | As Revised |
| | <u>January 3, 2003</u> | <u>January 3, 2003</u> | <u>December 28, 2001</u> | <u>December 28, 2001</u> |
| Deferred tax asset non-current | | No Change | \$ 3,982 | \$ 3,828 |
| Accumulated deficit | \$ (41,421) | \$ (40,789) | \$ (24,263) | \$ (24,011) |
| Notes receivable from officers and directors | \$ (3,064) | \$ (3,696) | \$ (3,458) | \$ (3,864) |

F-27

INDEPENDENT CERTIFIED PUBLIC ACCOUNTANTS

REPORT ON SCHEDULE

To the Board of Directors

STAAR Surgical Company

The audits referred to in our report dated February 21, 2003 (except for Note 18 which is dated March 26, 2003), relating to the restated consolidated financial statements of STAAR Surgical Company and Subsidiaries, which is contained in Item 8 of this Amendment No. 3 to Annual Report on Form 10-K included the audit of Schedule II, Valuation and Qualifying Accounts and Reserves as of January 3, 2003, and for each of the three years in the period ended January 3, 2003. This financial statement schedule is the responsibility of the Company's management. Our responsibility is to express an opinion on this financial statement schedule based on our audit.

In our opinion, such financial statement schedule presents fairly, in all material respects, the information set forth therein.

BDO SEIDMAN, LLP

Los Angeles, California

February 21, 2003

(except for Note 18 which is dated March 26, 2003 and Notes 6 and 19 which are dated November 17, 2003)

INDEPENDENT CERTIFIED PUBLIC ACCOUNTANTS CONSENT

To the Board of Directors

STAAR Surgical Company

We consent to incorporation by reference in the Registration Statement (No. 333-45810), (No. 333-51064), (No. 333-52096), (No. 333-60241), and (No. 333-90018) on Form S-8 and (No. 333-47820) on Form S-3 of STAAR Surgical Company of our report dated February 21, 2003 (except for Note 18 which is dated March 26, 2003 and Notes 6 and 19 which are dated November 17, 2003) relating to the restated consolidated balance sheets of STAAR Surgical Company and Subsidiaries as of January 3, 2003 and December 28, 2001 and the related restated consolidated statements of operations, stockholders' equity and comprehensive income, and cash flows and related schedule for each of the three years in the period ended January 3, 2003, which report appears in the January 3, 2003 Amendment No. 3 to Annual Report on Form 10-K of STAAR Surgical Company and subsidiaries.

BDO SEIDMAN, LLP

Los Angeles, California

November 19, 2003

F-29

STAAR SURGICAL COMPANY AND SUBSIDIARIES

SCHEDULE II VALUATION AND QUALIFYING ACCOUNTS AND RESERVES

| <u>Column A</u> | <u>Column B</u> | <u>Column C</u> | <u>Column D</u> | <u>Column E</u> |
|--|---|------------------|-------------------|---------------------------------------|
| <u>Description</u> | <u>Balance at Beginning of Year</u> | <u>Additions</u> | <u>Deductions</u> | <u>Balance at End of Year</u> |
| (In thousands) | | | | |
| 2002 | | | | |
| Allowance for doubtful accounts deducted from accounts receivable in balance sheet | \$ 768 | \$ 1,186 | \$ 1,149 | \$ 805 |
| Accrued restructuring costs | 100 | | 100 | |
| Deferred tax asset valuation allowance | 4,288 | 14,319 | | 18,607 |
| Notes receivable reserve | 3,609 | | 1,814 | 1,795 |
| | <u>\$ 8,765</u> | <u>\$ 15,505</u> | <u>\$ 3,063</u> | <u>\$ 21,207</u> |
| 2001 | | | | |
| Allowance for doubtful accounts deducted from accounts receivable in balance sheet | \$ 781 | \$ | \$ 13 | \$ 768 |
| Accrued restructuring costs | 2,236 | 100 | 2,236 | 100 |
| Deferred tax asset valuation allowance | 1,511 | 2,777 | | 4,288 |
| Notes receivable reserve | 1,500 | 2,109 | | 3,609 |
| | <u>\$ 6,028</u> | <u>\$ 4,986</u> | <u>\$ 2,249</u> | <u>\$ 8,765</u> |
| 2000 | | | | |
| Allowance for doubtful accounts deducted from accounts receivable in balance sheet | \$ 373 | \$ 408 | \$ | \$ 781 |
| Accrued restructuring costs | | 4,236 | 2,000 | 2,236 |
| Deferred tax asset valuation allowance | | 1,511 | | 1,511 |
| Notes receivable reserve | | 1,500 | | 1,500 |
| | <u>\$ 373</u> | <u>\$ 7,655</u> | <u>\$ 2,000</u> | <u>\$ 6,028</u> |