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**New Rec: STAAR Surgical (STAA: \$11.86) September 15, 2003**

**Position: Sell      Target: \$6      Timing: 2 (1=aggressive; 5=cautious)**

MM\$	Q3 03e	Q4 03e	Q1 04e	Q2 04e	2003e	2004e	2005e
<b>Revs</b>	<b>12.45</b>	<b>14.12</b>	<b>13.51</b>	<b>14.05</b>	<b>52.35</b>	<b>56.50</b>	<b>60.90</b>
<b>EPS\$</b>	<b>-0.05</b>	<b>-0.03</b>	<b>0.00</b>	<b>0.00</b>	<b>-0.18</b>	<b>0.02</b>	<b>0.17</b>
<b>Y/Y Gro</b>	<b>n/a</b>	<b>n/a</b>	<b>n/a</b>	<b>n/a</b>	<b>n/a</b>	<b>n/a</b>	<b>649%</b>
<b>PE</b>	<b>n/a</b>	<b>n/a</b>	<b>n/a</b>	<b>n/a</b>	<b>n/a</b>	<b>534.86</b>	<b>71.41</b>
<b>PSR</b>	<b>n/a</b>	<b>n/a</b>	<b>n/a</b>	<b>n/a</b>	<b>4.10</b>	<b>3.80</b>	<b>3.52</b>
<b>Consen</b>	<b>-0.05</b>	<b>-0.03</b>	<b>0.00</b>	<b>0.01</b>	<b>-0.18</b>	<b>0.10</b>	<b>0.34</b>

**Shares Out: 18.1M**

**Market Cap: \$215M**

**FYE: Dec**

Summary: STAAR Surgical was incorporated in 1982 and develops, manufactures, and distributes ophthalmologic products for treating refractive conditions, cataract and glaucoma. Most of STAA's revenues come from the cataract IOL (intraocular

lens) segment, which accounted for 94% of total revenues in 2001, 91% of total revenues in 2002 and H1 2003. Glaucoma represents only about 2%-4% of revenues.

Investor focus is now nearly entirely concentrated on STAA's refractive segment. This business unit develops and manufactures an ICL (implantable contact lens) which is surgically implanted behind the iris and in front of the eye's natural lens to correct refractive disorders. STAA says that the ICL has gained approval in 37 countries over the last eight years. In 2001 ICL revenue represented 3.6% of STAA's total revenue, in 2002 it was at 5% and in H1 2003 6.6%.

STAA shares have had a terrific run in 2003, rising 189% year to date versus NASDAQ's increase of 33% year to date. Investor excitement stems from STAA's hoped for introduction of the ICL into the U.S. market at the start of 2004. STAA is appearing before a FDA Panel on October 3, 2003. Official approval is expected early in 2004. The company has stated its intention to make the ICL family of products the "dominant revenue generator for the company over the next four to five years."

The "street" estimate of the annual run rate of STAA's share of the U.S. market for phakic IOLs a few years out is 78,000 eyes, or units, annually. At an ASP of \$600 per unit, the "street" anticipates a revenue run rate of \$47M annually.

Our research indicates that the current optimism regarding the ICL business is most probably unwarranted. STAA is seeking labeling in the U.S. to treat patients in the diopter range of -3D to -20D. We think that only patients with diopters of below -10D would be candidates for the procedure, and only rarely will patients over -8D receive an ICL. The reasons are that (1) this procedure is much higher risk than LASIK, which is the standard of care and which is non-invasive, and which is typically used on patients up to -10D, (2) the ICL insertion procedure is expensive (about \$2500-\$3000 per eye) and would typically have to be paid out of pocket, (3) only highly skilled surgeons can perform the procedure, which limits the penetration, and (4) STAA's ICL will soon have competition from Ophtec, CIBA and Alcon, all of which have developed solutions for the same indication. Notably, Ophtec's phakic IOL has a 60%+ market share in Europe versus STAA's ICL market share of 25%.

We think that a realistic estimate of an annual unit run rate for this group of products, i.e. phakic IOLs, in the U.S. is 20,000-25,000 units. We arrived at that figure through consulting with several industry experts. This is about the number of units that are used annually outside the U.S. in refractive procedures and the market outside the U.S. has been in existence for over 17 years. We note that the unit volumes outside the U.S. include phakic IOLs with indications for hyperopia

and astigmatism. The first generation of phakic IOLs in the U.S. will be labeled only for myopia.

We contrast our estimate of the entire market with the “street’s” estimate of the annual run rate just for STAA’s ICL at over 78,000 units, which is three to four times our estimate for the entire market, not STAA’s share. We think that STAA could at best capture about 35%-45% market share in the long run at 9,000 ICLs per year. At an ASP of \$600 per ICL, the revenue run rate becomes \$5.4M, which is far from the “street’s” estimated annual sales run rate of \$47M a few years out from product launch.

In the opinion of experts we polled, 2004 and 2005 should be ramp-up years for the entire U.S. phakic IOL market. Still, the “street” expects STAA to place about 5,500 ICLs in 2004 and about 15,000 ICLs in 2005. We estimate that STAA can place 4,000 ICLs in the U.S. in 2004 and 7,000 ICLs in the U.S. in 2005. The “street” also assumes that approval in the U.S. will result in further growth in ICL sales outside the U.S. We do not think that the U.S. approval will have much of an impact on sales outside the U.S., as this market is far more mature.

We also note, in support of our thesis, that since its market introduction in 1995 and despite approval in 37 countries worldwide, only 30,000 STAA ICLs in total have implanted. We think that our assessment of a run rate of 9,000 eyes in the U.S. as a run rate for STAA is very reasonable, if not optimistic.

The difference between our market size numbers and the “street” is that (1) the “street” includes in its market potential almost the full range of diopters that STAA is seeking, -3D to -20D, and (2) the “street” either assumes significant penetration levels of the low diopter patient base, who we think will clearly opt for LASIK, or much higher penetration levels of the high diopter patient base than the current penetration of LASIK or the current penetration of phakic IOLs in the market outside the U.S., which we think is unrealistic. Comparing the “street” ICL unit sales expectations in the U.S. in 2004 and 2005 against our assessment of the market size reveals that to meet “street” unit estimates STAA’s ICL would have to penetrate in 2004 between 20%-25% of our estimated 20,000-25,000 long-term unit run rate for the entire U.S. phakic IOL market and 60%-75% of the market run rate in 2005. Given the surgeon training required, plus the invasive nature of the operation and consumer unfamiliarity with the procedure, we think such a rapid penetration is highly unlikely.

STAA’s core business has been unprofitable since 1999. It is a low growth business at best, although some recent revenue trends have been negative. STAA’s core business revenues have declined from 2001 to 2002 and have remained relatively flat Y/Y in H1 2003. STAA is betting the farm on the ICL business.

We expect the catalyst for our story to work will be the realization that the market opportunity is not as large as the “street” estimates. This could be evident soon after the launch of the ICL in the U.S., although there is probably some pent up demand from patients who have not had good alternatives previously. Another catalyst could come sooner, however. If the FDA panel, or the FDA does not approve, which we doubt, or if it issues an approval for a lesser correction range than is hoped for, which is more likely, the shares could be impacted. This makes the timing of the sale of STAA shares more difficult. If full approval is given, the shares could rise, although we think virtually no-one doubts that approval will come. A partial approval, however, might result in a decline. We assume that some sort of approval will occur.

We value the company on a sum of parts basis. For the core business, which is hardly growing and is at a revenue run rate of about \$50M, we assign a 18X multiple to the most optimistic EPS that this business could generate on its own, which is \$0.20 according to the company. The core business is, thus, worth \$3.60 per share at best. We note that in 2004, if we were to exclude the U.S. ICL revenues and additional SG&A expenses, we think that the core business would generate only \$0.10 per share. We value the ICL business at best at \$2.50 per share, half attributable to the U.S. ICL business and the other half to ICL business outside the U.S. We arrive at \$1.25 per share for the U.S. business by assigning a 25X multiple to our EPS contribution at an eventual revenue run rate of \$5.4M per year, which would contribute about \$0.05 to the EPS. The \$5.4M run-rate would imply a 40%-45% U.S. market share for STAA in the phakic IOL market. However, we doubt that with the likes of Alcon in the market in several years, as we discuss below, STAA could maintain a 40% share for long. Nevertheless, we estimate that, at best, in the future, STAA might earn a company total of \$0.30 per share. Assigning a 20X P/E to that eventuality many years out we can see a value of \$6 per share without discounting the shares, which we use as our target.

For 2004 we estimate revenues of \$56.5M and EPS of \$0.02 versus the “street’s” estimate of revenues of \$61M and EPS of \$0.10. Then, for 2005 we expect STAA to generate revenues of \$60.9M and EPS of \$0.17 versus the “street’s” estimate of \$73M in revenues and EPS of \$0.34.

## Background

STAAR Surgical develops and manufactures medical devices that are used in ophthalmic surgery, mainly in cataract, refractive and glaucoma applications. Most of the company’s revenue comes from cataract IOLs (intraocular lens that is implanted during cataract surgery).

Cataract product revenue accounted for 94% of total revenue in 2001, 91% in 2002, and 91% in H1 2003. The company estimates that it has about 3% market share of the cataract IOL market. Some industry analysts estimate that the global cataract market grows 1%-3% annually. Major players in this market are Alcon at about 50% market share, Bausch and Lomb at about 13% market share, and Advanced Medical Optics at about 12% market share.

In the refractive segment, STAA sells ICL (implantable contact lens) in 37 countries worldwide. The product came on the market since 1995, but has gained approval in additional countries over the eight-year period it has been on the market for a current total of 37, according to the company. ICL is classified as a phakic IOL. The phakic IOL is implanted in the eye without removal of the eye's natural lens, in contrast with cataract surgery which removes the lens. The insertion of a phakic IOL corrects refractive errors in the eye so that the patient would not need to wear glasses or contacts.

STAA currently has about 25% market share of the world wide phakic IOL market, behind Ophtec, which has 60%+ market share. About 30,000 of STAA's ICL have been implanted worldwide since the product was created (including pre-approval clinical trials). In contrast about 500,000 of Ophtec's Artisan IOLs have been implanted for a wider variety of indications since the product's introduction in the mid 1980s, nearly 20 years ago. Revenues from the ICL product made up 3.6% of total revenue in 2001, 5% in 2002, and 6.6% in H1 2003.

STAA's glaucoma product is a device used in surgery to treat open-angle glaucoma. The revenues from this segment are insignificant and are expected to grow quickly off a small base but remain a small portion of the company's total revenues. Glaucoma products accounted for 1.7% of 2001 total revenue, 3.3% of total revenue in 2002, and 2.4% of total revenue in H1 2003. Glaucoma revenue was down Y/Y in H1 2003 and sequentially in Q2 2003.

The following table illustrates recent trends in the three revenue segments. We note that the company does not officially report revenue in segments.

(\$MM)	2001	2002	H1 2002	H1 2003
Cataract	47.508	43.87	21.508	23.426
Refractive	1.838	2.38	1.2	1.678
Glaucoma	0.89	1.59	0.89	0.625
Total	50.236	47.84	23.598	25.729

Y/Y	2001	2002	H1 2003
Cataract	-7.8%	-7.7%	8.9%
Refractive	-5.4%	29.5%	39.8%
Glaucoma	89.4%	78.7%	-29.8%
Total	-6.6%	-4.8%	9.0%

% Revenue	2001	2002	H1 2002	H1 2003
Cataract	94.6%	91.7%	91.1%	91.0%
Refractive	3.7%	5.0%	5.1%	6.5%
Glaucoma	1.8%	3.3%	3.8%	2.4%
Total	100.0%	100.0%	100.0%	100.0%

Source: company information provided to “street” analysts

The company sells its products in over 39 countries. Manufacturing sites are located in the United States and Switzerland. Domestic sales account for about 50% of the revenue and sales in Germany account for about 40% of the revenue.

## Discussion

1. LASIK is the current standard of care for permanent visual acuity correction of myopia through surgery.

LASIK is an acronym for Laser-Assisted In Situ Keratomileusis. We quote the description of the procedure from an FDA information web site:

LASIK is a procedure that permanently changes the shape of the cornea, the clear covering of the front of the eye, using an excimer laser. A knife, called a microkeratome, is used to cut a flap in the cornea. A hinge is left at one end of this flap. The flap is folded back revealing the stroma, the middlesection of the cornea. Pulses from a computer-controlled laser vaporize a portion of the stroma and the flap is replaced.

LASIK was introduced to the market in the early 1990s as an improvement to PRK (photo refractive keratotemy). Long time subscribers to our research will remember we wrote extensively about the market and the players in PRK beginning in 1990 and ending in 1996 with the financial collapse of Summit Technology (BEAM at the time), a pioneer in PRK, now owned by Alcon. In the U.S., LASIK is approved for myopia up to -15D with the VISX StarS2, up to -14D with the Nidek laser, and up to -14D with the Alcon/Summit. Since the market introduction of PRK about 5.2M eyes have reportedly been treated. Industry insiders estimate that this constitutes about 5% penetration of the total available eyes that would qualify as LASIK candidates.

In the last year or so, a new LASIK technology has been gaining popularity. This procedure is called Wavefront LASIK or Custom Ablation. In addition to

correcting myopia and astigmatism, as in LASIK, Wavefront LASIK also attempts to correct some higher-order aberrations that affect quality of vision, and results in fewer higher order aberrations as a result of the procedure when compared to LASIK, according to the literature. Wavefront LASIK is more costly than standard LASIK, but many industry experts think that Wavefront LASIK will soon rival the standard LASIK as the standard of care, as it is a more precise procedure. In our opinion, there is not yet enough data concerning outcomes and complications from Wavefront LASIK to make that judgment. One of the problems with the Wavefront procedure is that it requires that relatively more tissue be ablated than in the LASIK procedure.

PRK, LASIK and Wavefront LASIK are considered to be non-invasive procedures.

2. Industry insiders think that while the ICL solution may gratify clinical curiosities, its commercial applications are limited.

a. This notion is supported by the number of ICLs implanted since the introduction of the product. STAA's ICL was first introduced in 1995-1996 and has since been approved and used in 37 countries, according to the company. The company claims that about 30,000 eyes worldwide have been implanted with the ICL in total. This number includes all trials and post-approval procedures. However, TLC Vision, the most prominent refractive surgery center group in Canada, has implanted ICLs in only 20 eyes since the product was approved in Canada in 1998. Canada has always led the U.S. in change in the refractive surgery business, since approvals for procedures and certain equipment have come sooner in Canada than in the U.S. Canada's population is about 12% of the U.S. The approval regimen is easier still in Europe and in South America.

b. Industry insiders concur that procedures done for ICL clinical trials were performed by first-rate surgeons and that it is unrealistic to expect the same kind of results when ICL is commercialized for the mass market. Supporting this view, when ICL was first introduced in Europe, the incidence of cataract as a result of the procedure was about 20%. The ICL design has changed since the European introduction and is now reportedly resulting in a lower incidence of cataract. The company also claims that the rollout was not done properly in Europe in terms of training and that management intends to correct the problem with the U.S. rollout. However, our discussions with refractive surgeons lead us to think that there is more than just training at play here. Everyone with whom we have spoken has emphasized that ICL implantation requires substantial skills on the surgeon's part that can not be achieved just from training. Surgeons who do not normally perform similarly challenging procedures would not be good candidates for the ICL procedure. Thus, our anecdotal evidence suggests that the subset of surgeons that

should or will even attempt this procedure is much smaller than the “street” assumes, and is probably limited to cataract surgeons. Retina surgeons with whom we have spoken show no interest, and refractive surgeons who use lasers are unlikely to have the requisite surgical skills or to be willing to perform surgery in another facility.

One issue is over the difficulty of transferring knowledge and skills about how to perform this procedure from the expert surgeons. Many in the ophthalmic community are skeptical. The other issue is that even if that were possible, how quickly can this transfer of knowledge take place from a limited number of expert surgeons? Another question to ask is who will be the guinea pigs for the docs-in-training? How many ophthalmologists will refer their patients to doctors performing these procedures? Also, since the ICL insert procedure would only be applicable to a small population, it may not make sense for so many surgeons to be trained, as each would perform relatively few procedures. For many surgeons, the investment in time to train and perhaps even in money to build a surgical suite if they do not have one may not be financially attractive. We suspect that in practice only a select few first-rate surgeons will be performing the procedure and that patients interested in having the procedure done will seek out these few experts.

c. Yet another issue is determining which practices are conducive to performing this procedure. Most surgeons who only perform refractive procedures that were polled by industry experts would rather do LASIK and are not very interested in performing the ICL procedure. Most of these surgeons do not own a surgical suite. However, the insertion of an ICL must be performed in a surgical suite. The choice for a surgeon then becomes to either have a surgical suite built or to use a hospital surgical suite for a facility fee of about \$1,000 per procedure. In addition, surgeons who only perform refractive procedures are unlikely to have the skill required to perform the procedure.

Cataract surgeons are more likely to have the ability to master the technique and they also have access to surgical suites. However, cataract surgeons’ practices are designed around meeting the needs of seniors and are not designed to attract refractive patients. Further, cataract surgeons do not spend money to advertise, unlike the refractive surgeons. They have developed very strong internal marketing techniques that mostly rely on word of mouth and center around elderly patients. The unanswered question is if they can translate a similar form of internal marketing and have their older patients pull in their younger relatives.

There is a group of surgeons that do both refractive and cataract work. Those surgeons would be the best candidates for the procedure. However, the industry experts we consulted have said that they have not seen much interest in the procedure from this group of surgeons as a whole. In general, this group of

surgeons views this as a procedure that addresses a small population. Retina surgeons with whom we have spoken have no interest in doing refractive procedures and think that no serious retina surgeon would do these procedures.

d. Potential side effects of this procedure can be quite serious. This fact is important to consider as ICL implantation is an elective procedure. The side effect of any invasive procedure on the eye could be, in the worst-case scenario, the loss of the eye. This rarely happens, but it does happen. The most common complication from ICL insertion is cataract or the loss of the natural lens. This occurs if the ICL is not inserted precisely enough and makes contact with the natural lens. In contrast with the designs of all other phakic lenses that are planned to be on the market, the STAA lens is designed to be placed in the posterior chamber, behind the iris and in front of the lens, putting it in closer proximity to the natural lens than is the case with the competing designs, which place the device in the anterior chamber, in front of the iris. If cataracts occur, a surgical procedure is then required to remove the natural lens and replace it with an IOL (standard cataract surgery). In general, there is a concern about the amount of space between the iris and the natural lens. Some industry experts think that the space is too small to begin with and naturally shrinks over time.

e. The cost of this procedure is high compared to LASIK and, like LASIK, must be paid out of pocket. The entire procedure is expected to cost about \$2,500-\$3,000 per eye. For reference, the average cost of LASIK is \$1,200-\$1,700 per eye in the U.S.

□

### 3. Treatment for myopes in the range up to -10D

The company and the “street” assume that ICL will be used to treat patients that fall into the same diopter range that is routinely treated with LASIK. However, based on our conversations with industry experts and surgeons, and intuitively as well, we think that anyone considering taking refractive surgery action to correct myopia would first consider LASIK and only those patients not eligible for LASIK may consider ICL as an alternative. However, when the “street” calculates the market size, it includes as the target market all patients with diopters of -4D to -20D. Wavefront LASIK is approved to -6D and standard LASIK is typically used on patients with diopters up to -10D, although some lasers are approved up to -14D. Many LASIK centers have told us that they regularly correct vision in diopter range up to -10D.

Some “street” reports also cite the results from a study published in the Journal of Refractive Surgery (July/August 2003 issue), which compares two groups of patients, one of which had ICLs inserted and the other of which was treated with LASIK. The entire patient group had a mean level of myopia of -10

diopters. The results suggest that a higher percentage of patients implanted with the ICL had 20/20 corrected vision or better, as well as corrected vision of 20/40 or better. We spoke to a source familiar with the trial protocols. In the opinion of our source this study unfairly compares the two treatments. He explained that typically for a patient that exceeds  $-6$  diopters, two LASIK procedures are needed to correct the vision properly. For example, if a patient is a  $-10$  diopter, the first procedure would correct vision as if the patient were a  $-6D$  and the follow-on procedure would correct the remaining  $-4D$ . This is done so as not to overcorrect on the first pass. Our source said that in these trials the result of ICL implantation were compared to LASIK treatment after the first pass, when the patient's vision may not have been fully corrected.

#### 4. Treatment for myopes in the range between $-10D$ and $-20D$

We stated that LASIK is the standard of care for myopes up to  $-10D$ . For high/extreme myopes in the range  $-10D$  to  $-20D$  there are hardly any alternatives to glasses. One good option is to correct a very high myope to a low myope, able to see somewhat without glasses, then add glasses to get to 20/20. A surgical option that is widely employed is CLE/IOL, which stands for Clear Lens Extraction with Intraocular Lens Implantation. This surgical procedure corrects myopia by replacing the patient's natural lens with an IOL, as in cataract surgery. The difference is that the natural lens is extracted before cataract develops. As a side effect the patient loses accommodation ability in that eye, or the ability to focus. The procedure costs about \$2500 per eye and is usually performed on people who are above the age 50, especially if there are some signs of cataract developing anyway.

Industry experts have informed us that this procedure used to correct high refractive errors is not FDA approved but the off-label use is prevalent in the U.S. We polled a number of surgeons performing the procedure and found that on average these surgeons performed 1-2 such procedures per month. One industry expert estimates that about 20,000 CLE procedures are performed in the U.S. annually.

The experts we polled do not think that ICL will address the same patient population as the CLE/IOL. The experts see the ICL addressing a need for extreme myopes in the age range of 21 to 40 years old with household incomes of \$50,000+.

#### 5. Astigmatism in high myopes

A significant percentage of high myopes also have astigmatism. The phakic IOLs, including STAA's ICL, that are currently in the FDA approval pipeline do

not correct for astigmatism. Thus, anyone who undergoes the ICL procedure will not have perfectly corrected vision and will either need to still wear glasses or contacts or have LASIK done to correct for astigmatism. If a patient chooses to have the ICL inserted followed by a LASIK procedure, he or she is looking at spending about \$8,000-\$9,000 for the two surgeries. We think that the limitation of not treating astigmatism by the first generation of lenses in the approval pipeline could further reduce the near-term addressable market for the procedure due to extra cost, risk and overhead of undergoing two procedures.

## 6. Phakic IOLs

STAA's ICL also faces competition from phakic lenses developed by Ophtec (Artisan/Verisyse Phakic Lens), CIBA, and Alcon. Industry experts expect the STAA ICL to be first to market in early 2004 followed by Artisan/Verisyse IOL about six months later. CIBA and Alcon are expected to be on the market in early 2005 in the opinion of the industry insiders we polled. No one knew exact timelines for CIBA and Alcon. We have heard that CIBA Surgical is currently for sale. If that is the case, it remains to be seen who would gain distribution rights for the CIBA PRL (phakic IOL). Our sources also think that it is safe to assume that Bausch and Lomb and Advanced Medical Optics have phakic IOLs in development.

The Artisan/Verisyse IOL is developed by Ophtec, a privately held Dutch company, and will be distributed by Advanced Medical Optics in the United States. The phakic IOL attaches to the iris and requires an anterior placement, or placement in front of the iris. As we noted above, STAA's ICL is implanted behind the iris (posterior placement) and in front of the natural lens. Both procedures address the same problem.

We quote the technical details of the procedure from Ophtec's press release:

With its unique iris fixation method, OPHTEC's phakic IOL technology enables the lens to attach to the periphery of the iris in a way that does not inhibit the iris' function. Securely anchored, the lens vaults forward, occupying the space between the crystalline lens and the corneal endothelium and provides for the free flow of aqueous from the posterior to the anterior chamber. This type of anterior placement minimizes the risk of endothelial cell loss, as well as cataract formation associated with crystalline lens trauma.

Ophtec was the first to market in Europe and has a dominant market share in this space, somewhere above 60%. In contrast, STAA's market share in Europe is at about 25% according to the company. Some experts estimate that in Europe Ophtec's IOL is implanted about three times as frequently as STAA's ICL. The ASP of Ophtec's IOL is about 60% that of the ICL.

We consulted a number of industry experts to find out the reasons for Ophtec's larger market share. We were told that the key reason is the ease of insertion of the Ophtec phakic IOL versus STAA's ICL. The visibility is better in the anterior chamber and less skill is required to perform the procedure. The surgeon can see where the IOL is on the iris, whereas with the ICL there is no visibility of the lens behind the iris. The complication that could result out of the IOL is the scarring of the cornea versus potential cataract complication with the ICL. Ophtec's iris attachment keeps the IOL from the cornea, which minimizes the potential for complications altogether.

The Artisan lens is not foldable and thus requires an incision about twice the size (6mm) versus the one required for STAA's ICL. We learned, however, that Ophtec has a foldable version of its phakic IOL in development which could hit the market at the end of 2004 according to some estimates.

According to Ophtec, the phakic IOL has been used to correct visual acuity for about 17 years, during which time about 500,000 IOLs have been implanted worldwide. Ophtec is now seeking approval for its IOL in the US. The current PMA application is for the correction of near-sightedness, or myopia, in phakic eyes in the range of -5.0D to -20.0D. Our sources have told us that Ophtec is scheduled for the November 2003 FDA panel, only a month behind STAA.

7. An additional risk is that STAA's ICL has not yet been approved for use in the US, and even if approval does occur, it may not be for the hoped for indications.

The "street" assumes that STAA will get approval for the full -3D to -20D range. STAA's ICL will be considered at the October 3 FDA panel. The experts we polled think that there is some chance that STAA may not get approval for the full labeling range on the low end. This would make some intuitive sense, since implanting an ICL at the lower end seems a poor choice since it entails greater risk for little apparent benefit. This event would not affect our numbers, but it would reduce the "street's" perception of the potential market size for the ICL, and thus would impact the shares.

8. We think that the addressable population of ICL candidates in the U.S. is far lower than the "street" anticipates.

The "street" thinks that the potential market for the STAA ICL is 7.7M people or 15.4M eyes, which includes all the people at -4D and below. As we discussed earlier in the report, our sources have told us that the ICL makes no sense for anyone at or above -6D. Many have also said that in their opinion the true candidate population for the ICL should be comprised of people over -10D and in some unusual cases people over -8D.

A study published in the 1997 titled “Prevalence of Myopia in Adults: Implications for Refractive Surgeons” by McCarty et. al. finds that out of a large population of individuals in the U.S. ages 4-74, 43% had low myopia (less than -5D), 3.2% had high myopia (-5.01D to -10D) and 0.2% had extreme myopia (below -10D).

Several sources have confirmed that the population of below -6D represents about 2.5% of the myopic population. Further, those we polled thought that the population of -10D or below is about 0.3% of the myopic population according to industry surveys and literature.

A market research study estimated a total of 55M eligible myopes in the U.S. for LASIK surgery. Eligibility was adjusted according to age, since as patients age, they are less likely to undergo surgical refractive corrections. This would imply 165,000 extreme myopes in the diopter range of -10D and below. This population is tiny. The same source estimated that the population of eligible myopes in the ranges of -8D and below was about 2% of myopes or 1.1M people. Notably, this is just 14% of the size of the addressable population that the “street” estimates.

9. We think that revenue generated by the ICL in the U.S. will be much lower than the “street” anticipates.

The “street” assumes revenues from the U.S. sales of ICL to be in the range of \$3.2M-\$3.5M in 2004 and \$8.5M-\$9.4M in 2005. The ASP would range between \$500 and \$700 per lens or per eye. At an average price of \$600 per ICL, the “street” assumes that 5,333-5,833 ICLs would be inserted in the U.S. in 2004 and 14,167-15,667 ICLs would be implanted in 2005.

First, we contrast these figures with the 30,000 eyes that have been implanted with STAA’s ICL worldwide in the last eight years. On average, the “street” assumes that about 20,000 ICLs would be implanted in the U.S. in the next two years or 66% of the total number of ICLs that have been implanted in ICLs eight-year history.

Second, we can look at the worldwide annual unit volume of phakic IOLs, which was reported to be 20,000 in 2001. We note that phakic IOLs have been used in Europe for at least fifteen years prior to 2001. This unit volume covers hyperopic and toric indications that will not be approved in the U.S. anytime soon. As we noted earlier, STAA has about 25% market share of this volume, supplying ICLs for about 5,000 procedures each year. The experts with whom we spoke estimate the run rate unit volumes for all phakic IOLs in the U.S. should eventually

be comparable with the rest of the world at around 20,000-25,000 units per year. Some experts have indicated that there will be a ramp up period in the first couple of years as surgeons must undergo training to perform the procedure and consumers must accept it. STAA currently has only two people who will do the training and expects to expand that team to ten by the end of the year. Further, the worldwide numbers include products with indications that will not be approved in the U.S. in 2004, perhaps not even in 2005. Thus, the actual volume run rate in the U.S. could prove to be even lower. The “street” expectations for 2004 put STAA’s U.S. revenues for the ICL at 20%-25% of the total run-rate volume that currently exists after many years of penetration outside the U.S., and “street” expectations for 2005 imply that STAA would get 60%-75% of the current run-rate volume that exists outside the U.S. This type of ramp and penetration seems far too aggressive.

Third, there are ways we can estimate what the annual run rate for all phakic IOLs should be in the U.S. Currently in the U.S. about 1.2M eyes are treated with LASIK each year, or about 10% of the age-adjusted eligible population. We stated earlier in the report that approximately 1.1M people fall into the category of eligible myopes in the range of -8D and below. If 10% of that population gets the procedure done per year, a penetration like that of LASIK, this results in 22,000 phakic IOL procedures done per year. This is consistent with the estimate our sources arrived at using data from the phakic IOL market outside the United States. Remember that LASIK is not considered to be an invasive procedure, is much cheaper than ICL, and it can be performed more easily than an ICL insertion, so the actual penetration percentage could be lower than that of LASIK.

The company and some “street” reports put the annual run-rate opportunity for ICL in the U.S. at \$47M, which translates to about 78,333 ICLs per year, which is between three and four times our estimated annual run rate for the entire phakic IOL market in the U.S. We think that eventually a reasonable run rate for STAA would be 9,000 ICLs per year or 35%-45% share of the whole phakic IOL market. We think that meeting “street” estimates for ICL in 2004, about 5,500 procedures, even though it is lower than our run rate figure at maturity, should be challenging for STAA because penetration rates should remain low due to execution and training and doctor and consumer acceptance required to ramp up in procedure volume. We think that the 2005 estimates for ICL in the U.S. are too high for these reasons as well, plus given the competition that will come on the market from Ophtec, and potentially from CIBA and Alcon. Our estimate is that STAA can place 4,000 ICLs in the U.S. in 2004 and 7,000 ICLs in the U.S. in 2005.

## 10. Core business

STAA’s core business revenues have declined from 2001 to 2002 and have remained relatively flat Y/Y in H1 2003. We also note that STAA has not been

profitable since 1999.

Our industry sources have told us that STAA is viewed as an innovative company by MDs. However, given its limited product line, it is only the very loyal MDs who purchase from STAA. The reason is that MDs need many other surgical supplies for cataract surgery and it is more work to order from multiple companies. Our sources do not expect STAA's cataract business to take much share, but to only grow with the market, which is in the mid-single digit growth range. The "street" seems to agree with that assessment. Our model, too, reflects this assessment for this segment.

The "street" appears to be very enthusiastic about AquaFlow, STAA's device that is surgically implanted to treat open-angle glaucoma. The "street" projects growth of 30% each year for the next three years off a small base of \$1.3M in 2002. Industry experts whom we have consulted have indicated that there exists a strong bias in the medical community to treat glaucoma with pharmaceuticals and not with surgery. Only about 120,000 conventional surgeries are performed a year to treat glaucoma out of 3M cases (or 4% of patients are treated surgically). Our sources think that this number will shrink further. Additionally, we were told that AquaFlow would be applicable for use for a very small percentage of glaucoma cases. Our model agrees with the "street" numbers on AquaFlow, but we do point out that we think that these numbers may prove optimistic. AquaFlow revenues are down almost 30% Y/Y in H1 2003 and STAA appears to be placing support behind ICL as opposed to the AquaFlow.

## 11. Valuation

The "street" attributes a 4X 2004 revenue multiple to STAA shares. However, we note that all but \$5M-\$8M of the \$60M revenue number is the core business, which is not growing. Thus if we assume that the core business gets 1X multiple, the projected ICL business is getting a 25X sales multiple.

As we think the company will not make much money even when the ICL business is mature, which is in many years, we prefer to value this business as a sum of two parts, the core business and the ICL opportunity. The core business has a run-rate of about \$50M per year and in the best case scenario, according to the company, can generate EPS of \$0.20. If we assign a 18X P/E multiple we come up with a valuation of \$3.60 per share. We note that the core business has been unprofitable since 1999. It is nowhere near generating \$0.20 in EPS per year. We estimate that in 2004, without the additional SG&A spending for ICL, the core business could do \$0.10 in EPS.

To value the U.S. ICL business we assume an eventual annual run rate of 9,000 ICLs per year (or 35%-45% market share). This would result in about \$5.4M revenue per year. If we put a 4X multiple on that revenue stream, as is the case in the “street” valuations, we get \$1.20 per share. If we approximate that the \$5.4M in high margin revenue from the ICL would net \$0.05 per share in EPS and we put a 25X multiple on that, we get \$1.25 per share for this business. Similarly, we value the European ICL business at \$1.25 per share.

All in all, we get to a total future valuation for the company of \$6 per share using a generous sum of parts approach. Our EPS projections are -\$0.18 in 2003, \$0.02 in 2004 and \$0.17 in 2005. Even with the ICL business at maturity, with revenue of \$5.4M per year from the U.S. and \$6M outside the U.S., we estimate the company can earn at most \$0.30 per share in 2007 at the earliest. Discounted back to the present, the company would not be worth \$6 per share today on an EPS basis. Nevertheless, we will make \$6 our target.

## 12. Financial projections

(\$MM)	2002	2003e	2004e	2005e
Cataract	43.87	47.28	47.70	49.00
Refractive	2.38	3.58	6.80	9.40
Glaucoma	1.59	1.45	2.00	2.50
Royalty/Other	0.41	0.05	0.00	0.00
Revenue	48.25	52.35	56.50	60.90
COGS	24.10	23.56	22.60	22.53
Gross profit	24.15	28.78	33.90	38.37
SG&A	25.79	26.67	29.50	30.00
R&D	4.02	5.08	4.80	5.00
Operating income	-5.66	-2.96	-0.40	3.37
Interest, net (exp)	-0.51	0.95	1.00	1.20
Income before tax	-6.17	-2.01	0.60	4.57
Tax (benefit)	-0.36	1.23	0.19	1.46
Minority interest	0.25	0.02	0.00	0.00
Net income	-6.06	-3.26	0.41	3.11
EPS	-0.35	-0.18	0.02	0.17
S/O	17.176	17.916	18.4	18.7

Y/Y	2002	2003e	2004e	2005e
Cataract	-8%	8%	1%	3%
Refractive	29%	50%	90%	38%
Glaucoma	79%	-9%	38%	25%
Royalty/Other	-26%	-88%	-100%	0%
Revenue	-5%	8%	8%	8%
COGS	11%	-2%	-4%	0%
Gross profit	-17%	19%	18%	13%
SG&A	-10%	3%	11%	2%
R&D	6%	26%	-5%	4%
Operating income	n/a	n/a	n/a	n/a
Interest, net (exp)	n/a	n/a	6%	20%
Income before tax	n/a	n/a	n/a	661%
Tax (benefit)	n/a	n/a	n/a	661%
Minority interest	83%	-93%	-100%	0%
Net income	n/a	n/a	n/a	661%
EPS	n/a	n/a	n/a	649%
S/O	1%	4%	3%	2%
% Revenue	2002	2003e	2004e	2005e
Cataract	91%	90%	84%	80%
Refractive	5%	7%	12%	15%
Glaucoma	3%	3%	4%	4%
Royalty/Other	1%	0%	0%	0%
Revenue	100%	100%	100%	100%
COGS	50%	45%	40%	37%
Gross profit	50%	55%	60%	63%
SG&A	53%	51%	52%	49%
R&D	8%	10%	8%	8%
Operating income	n/a	n/a	n/a	6%
Interest, net (exp)	n/a	2%	2%	2%
Income before tax	n/a	n/a	1%	7%
Tax (benefit)	n/a	2%	0%	2%
Minority interest	1%	0%	0%	0%
Net income	n/a	n/a	1%	5%

(\$MM)	1Q 03	2Q 03	3Q 03e	4Q 03e
Cataract	11.529	11.897	11.1	12.75
Refractive	0.85	0.828	0.9	1
Glaucoma	0.4	0.225	0.45	0.37
Royalty/Other	0.047	0.001	0.00	0.00
Revenue	12.826	12.951	12.45	14.12
COGS	5.847	5.9	5.60	6.21
Gross profit	6.979	7.051	6.85	7.91
SG&A	6.448	6.6	6.62	7.00
R&D	1.176	1.4	1.20	1.30
Operating income	-0.645	-0.949	-0.97	-0.39
Interest, net (exp)	0.245	0.2	0.30	0.20
Income before tax	-0.4	-0.749	-0.67	-0.19
Tax (benefit)	0.329	0.3	0.30	0.30
Minority interest	0.018	0	0.00	0.00
Net income	-0.747	-1.049	-0.97	-0.49
EPS	-0.04	-0.06	-0.05	-0.03
S/O	16.962	18.1	18.25	18.35
Y/Y	1Q 03	2Q 03	3Q 03e	4Q 03e
Cataract	10%	8%	9%	5%
Refractive	42%	38%	64%	59%
Glaucoma	-18%	-44%	29%	6%
Royalty/Other	-67%	-99%	-100%	-100%
Revenue	9%	7%	11%	7%
COGS	-3%	-3%	0%	-3%
Gross profit	22%	17%	22%	16%
SG&A	1%	-3%	9%	8%
R&D	9%	43%	20%	35%
Operating income	n/a	n/a	n/a	n/a
Interest, net (exp)	n/a	n/a	n/a	n/a
Income before tax	n/a	n/a	n/a	n/a
Tax (benefit)	n/a	n/a	n/a	n/a
Minority interest	-56%	-100%	-100%	-100%
Net income	n/a	n/a	n/a	n/a
EPS	n/a	n/a	n/a	n/a
S/O	-1%	5%	6%	7%

% Revenue	1Q 03	2Q 03	3Q 03e	4Q 03e
Cataract	90%	92%	89%	90%
Refractive	7%	6%	7%	7%
Glaucoma	3%	2%	4%	3%
Royalty/Other	0%	0%	0%	0%
Revenue	100%	100%	100%	100%
COGS	46%	46%	45%	44%
Gross profit	54%	54%	55%	56%
SG&A	50%	51%	53%	50%
R&D	9%	11%	10%	9%
Operating income	n/a	n/a	n/a	n/a
Interest, net (exp)	2%	2%	2%	1%
Income before tax	n/a	n/a	n/a	n/a
Tax (benefit)	3%	2%	2%	2%
Minority interest	0%	0%	0%	0%
Net income	n/a	n/a	n/a	n/a
(\$MM)	1Q 04e	2Q 04e	3Q 04e	4Q 04e
Cataract	11.7	11.85	11.55	12.6
Refractive	1.36	1.7	1.82	1.92
Glaucoma	0.45	0.5	0.5	0.55
Royalty/Other	0	0	0	0
Revenue	13.51	14.05	13.87	15.07
COGS	5.404	5.62	5.548	6.028
Gross profit	8.106	8.43	8.322	9.042
SG&A	7.1	7.4	7.5	7.5
R&D	1.20	1.20	1.10	1.30
Operating income	-0.19	-0.17	-0.28	0.24
Interest, net (exp)	0.25	0.25	0.25	0.25
Income before tax	0.06	0.08	-0.03	0.49
Tax (benefit)	0.02	0.03	-0.01	0.16
Minority interest	0.00	0.00	0.00	0.00
Net income	0.04	0.05	-0.02	0.33
EPS	0.00	0.00	0.00	0.02
S/O	18.4	18.4	18.4	18.4

Y/Y	1Q 04e	2Q 04e	3Q 04e	4Q 04e
Cataract	1%	0%	4%	-1%
Refractive	60%	105%	102%	92%
Glaucoma	13%	122%	11%	49%
Royalty/Other	-100%	-100%	0%	0%
Revenue	5%	8%	11%	7%
COGS	-8%	-5%	-1%	-3%
Gross profit	16%	20%	22%	14%
SG&A	10%	12%	13%	7%
R&D	2%	-14%	-8%	0%
Operating income	n/a	n/a	n/a	n/a
Interest, net (exp)	2%	25%	-17%	25%
Income before tax	n/a	n/a	n/a	n/a
Tax (benefit)	n/a	n/a	n/a	n/a
Minority interest	-100%	0%	0%	0%
Net income	n/a	n/a	n/a	n/a
EPS	n/a	n/a	n/a	n/a
S/O	8%	2%	1%	0%

% Revenue	1Q 04e	2Q 04e	3Q 04e	4Q 04e
Cataract	87%	84%	83%	84%
Refractive	10%	12%	13%	13%
Glaucoma	3%	4%	4%	4%
Royalty/Other	0%	0%	0%	0%
Revenue	100%	100%	100%	100%
COGS	40%	40%	40%	40%
Gross profit	60%	60%	60%	60%
SG&A	53%	53%	54%	50%
R&D	9%	9%	8%	9%
Operating income	n/a	n/a	n/a	n/a
Interest, net (exp)	2%	2%	2%	2%
Income before tax	0%	1%	0%	3%
Tax (benefit)	0%	0%	0%	1%
Minority interest	0%	0%	0%	0%
Net income	n/a	n/a	n/a	2%